(1) No. 96 575 OCT 10 1996

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

BRACCO DIAGNOSTICS INC. AND
BRACCO INTERNATIONAL B.V.,

Petitioners,

v.

DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, AND
BRUCE A. LEHMAN, ASSISTANT SECRETARY OF COMMERCE
AND COMMISSIONER OF PATENTS AND TRADEMARKS,

Respondents,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

At issue is the proper interpretation of the landmark Uruguay Round Agreements Act, which was intended to harmonize U.S. patent law with international law by amending 35 U.S.C. § 154 to provide for a new 20-year-from-application patent term for all U.S. patents in force on June 8, 1995 and issued thereafter.

The question presented is whether patents in force on June 8, 1995 by virtue of a Hatch-Waxman restoration extension pursuant to 35 U.S.C. § 156 are entitled under Section 154 to the same recalculation of patent life based on the new 20-year term as patents otherwise in force on June 8, 1995.

RULE 29.6 STATEMENT AND PARTIES TO THE PROCEEDING

This Petition is filed on behalf of Bracco Diagnostics Inc. and Bracco International B.V., which do not have any non-wholly-owned subsidiaries. Bracco S.p.A. is the parent company of Bracco Holding B.V. which in turn owns Bracco USA Inc., which in turn owns Bracco Diagnostics Inc. Bracco S.p.A. is the parent company of Bracco International B.V. which has no subsidiaries. In addition to the parties listed in the caption, the other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Merck & Co., Inc. and MSD Technology L.P., Schering Corporation, Hoffman-La Roche, Inc. and Syntex (U.S.A.) Inc., and Organon, Inc.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Bracco Diagnostics Inc. and Bracco International B.V. (collectively "Bracco" or "Petitioner") respectfully petition for a Writ of Certiorari to issue to review the judgment and opinion of the United States Court of Appeals for the Federal Circuit ("Federal Circuit") in this case, entered on April 4, 1996.

OPINIONS BELOW

The opinion of the Federal Circuit is reported at 80 F.3d 1543 (Fed. Cir. 1996) *(1a-20a)*[1]. The opinion of the United States District Court for the Eastern District of Virginia ("District Court") is reported at 903 F. Supp. 964 (E.D. Va. 1995) *(23a-28a)*.

The "Final Determination" of the United States Patent and Trademark Office ("PTO") at issue is published at 60 Fed. Reg. 30,069 (June 7, 1995) *(41a-48a)*. The United States Food and Drug Administration ("FDA") "Notice" at issue is published at 60 Fed. Reg. 37,652 (July 21, 1995) *(49a-53a)*.

JURISDICTION

The Federal Circuit entered its judgment on April 4, 1996 *(21a-22a)*, and denied three combined petitions for rehearing and suggestions for rehearing *en banc*, including that of Bracco, on July 12, 1996 *(35a-40a)*. The District Court entered its amended order pursuant to the Federal Circuit's

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[1] References to the Appendix hereto are cited as "*(__a)*".

decision on September 5, 1996 *(31a-34a)*. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions, set forth in full in the Appendix, are:

A. The Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994), to the extent codified at 35 U.S.C. § 154 *(54a-56a)*.

B. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the extent codified at 35 U.S.C. § 156 *(56a-73a)*.

STATEMENT OF THE CASE

This case involves the interrelationship between the recently enacted Uruguay Round Agreements Act ("URAA") to the extent codified at 35 U.S.C. § 154 *(54a-56a)*, and the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act") to the extent codified at 35 U.S.C. § 156 *(56a-73a)*.

In order to meet its international obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs"),[2] an agreement resulting from the Uruguay Round of multilateral trade negotiations conducted under the auspices of the General Agreement on Tariffs and Trade ("GATT"), the U.S. Congress passed the URAA in 1994. The purpose of the URAA, *inter alia*, was to harmonize the terms of patents issued in the United States with the 20-year-from-application term available in most other industrialized

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[2] Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs"), H.R. Doc. No. 316, 103d Cong., 2d Sess. at 1621 (1994).

nations.[3] *See* 35 U.S.C. § 154(a)(2) *(54a)*. Prior to enactment of the URAA, Section 154 provided that the term of a patent granted in the United States expired 17 years from the date the patent issued. For transitional purposes, the URAA amended Section 154(c)(1) to provide that "the term of a patent that is in force on [June 8, 1995, the effective date of the URAA,] shall be the greater of the 20-year term . . . or 17 years from grant . . . ." 35 U.S.C. § 154(c)(1) *(56a)*.

The Hatch-Waxman Act, passed in 1984, was designed to ensure an adequate incentive for continued development of new drugs by providing a restoration extension for the term of a pioneer drug patent to partially compensate for delay encountered by the patentee in obtaining FDA approval to market a product covered by the patent.[4] The Act struck a delicate balance between the interests of generic drug manufacturers and pioneer drug producers by also permitting generic drug manufacturers to rely on a pioneer drug producer's research as evidence that the generic copy of the pioneer drug is safe and effective.

Petitioners Bracco Diagnostics Inc. and Bracco International B.V. are the exclusive licensee and assignee in the United States, respectively, of U.S. Patent 4,001,323, which covers the active ingredient Iopamidol, an iodinated contrast agent. The

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[3] Letter from Donna Shalala, Sec'y, U.S. Dep't of Health and Human Servs., to U.S. Senator David Pryor (Feb. 26, 1996).

[4] H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1 (1984) ("The purpose of . . . the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.")

application for the patent covering Iopamidol was filed on November 24, 1975, and the patent issued on January 4, 1977.

The FDA did not approve marketing of products containing Iopamidol in the United States for almost nine (9) years. To partially compensate for this delay, the FDA granted Bracco a two-year patent restoration extension under the Hatch-Waxman Act.[5] Application of this restoration extension to the pre-URAA 17-year patent term resulted in a patent expiration date of January 4, 1996. Applying the two-year restoration extension to the 20-year patent term provided by the URAA would change the expiration of Bracco's patent term to November 24, 1997.

After the enactment of the URAA, Petitioner and other plaintiffs applied to the FDA for publication of their revised patent expiration dates based upon Section 154(c)'s new 20-year term of patent plus the two-year Hatch-Waxman restoration extension. The FDA, however, did not publish revised expiration dates, basing its refusal on a "Final Determination" issued by the PTO stating that a patent utilizing the 20-year term provided by Section 154(c) was not entitled to receive a restoration extension under Section 156 *(49a)*. The PTO took the position that a patent holder had the choice of the 17-year-from-issuance term plus the restoration extension or the 20-year-from-filing term without the extension *(45a)*. Its stated rationale *(43a)* was based on Section 156(a) of the Hatch-Waxman Act, which provided that the term of patent "shall be extended in accordance with this section from the *original expiration date* of the patent . . . ."

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[5] Because the Bracco patent was in the regulatory process when the Hatch-Waxman Act was passed in 1984, the maximum restoration period available was 2 years rather than the 5 years for patents that later entered the process. 35 U.S.C. § 156(g)(6) *(71a-73a)*.

(Emphasis supplied) *(56a)*. Since all of the patents at issue prior to June 8, 1995 were granted a 17-year term of patent, the PTO concluded that any restoration extension could only be applied to the "original expiration date" of that patent term, *i.e.*, to the end of the 17-year period *(45a)*.

The District Court overturned the FDA/PTO determination holding that the Hatch-Waxman restoration extension was to be added to the "patent term" set forth in Section 154(c), whether it be 17 or 20 years *(28a)*. The court concluded that the "original expiration date" to which § 156(a) applied was extended by the URAA because the URAA "effected a change in the [patent] 'term' as used in § 156(a) and § 154(c)." *(27a)*. Therefore, the court held that all patents in force on June 8, 1995, including Bracco's patent, were statutorily entitled to have the Hatch-Waxman restoration extension apply to the new 20-year term *(28a)*.

The Federal Circuit affirmed in part and reversed in part, holding that all patents in force on June 8, 1995 were entitled to receive applicable Hatch-Waxman restoration extensions except for those patents (such as Bracco's) in force on that date solely by virtue of a Hatch-Waxman extension *(19a)*. The court reasoned that any post-URAA extension for such patents would be a "second" extension in violation of Section 156(a)(2), which provides that a restoration extension shall be given provided "the term of the patent has never been extended under subsection (e)(1) of this section[.]" *(18a)*. The Federal Circuit concluded that Petitioner had already received an extension under subsection (e)(1) and thus was prohibited from what it perceived as the receipt of another extension at the end of the new URAA patent term *(18a)*.

No other appellate court has considered this issue because of the exclusive jurisdiction conferred upon the Federal

Circuit with respect to appeals of patent disputes. 28 U.S.C. § 1338.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Disregard of the URAA's Language and Radically Disparate Treatment Of Patents In Force On the URAA's Effective Date Undermine The United States' Ability To Secure Non-Discriminatory Protection of Intellectual Property Rights Worldwide

The Federal Circuit's disregard of the statutory language of the URAA and radically disparate treatment of patents in force on its effective date undermine the overarching intent of the URAA to reinforce the United States' leadership role in securing non-discriminatory protection of intellectual property rights worldwide.[6] At the Uruguay Round of negotiations conducted under the auspices of the GATT, the United States fought long and hard to establish a multilateral framework covering intellectual property.[7] The TRIPs agreement, the result of the United States' persistent efforts in this regard, is a crucial step toward eliminating and preventing discrimination in the protection of intellectual property

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[6] *See* Message from the President of the United States Transmitting the Uruguay Round Trade Agreements, Texts of Agreements, Implementing Bill, Statement of Administrative Action, and Required Supporting Statements, H.R. Doc. No. 316, Vol. 1, 103d Cong., 2d Sess., at 1 (1994); Additional Views by the Honorable Philip M. Crane, H.R. Rep. No. 128, 103d Cong., 1st Sess. (1993).

[7] Testimony of William Brock, FDCH Congressional Testimony (Feb. 27, 1996).

rights.[8] Indeed, Article 27:1 of the TRIPs agreement states that "patents shall be available and patent rights enjoyable *without discrimination* as to the place of invention, the field of technology and whether products are imported or locally produced." TRIPs at Article 27:1 (emphasis supplied).

In the URAA, Congress not only demonstrated its commitment to the TRIPs agreement by stating its intent to accelerate the implementation of TRIPs,[9] but also set forth therein the more far-reaching objectives of the United States regarding the full protection of intellectual property rights. Specifically, the URAA states that it is the United States' objective to "supplement and *strengthen* the standards of [TRIPs],"[10] "to prevent or *eliminate discrimination* with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights,"[11] and "to secure fair, *equitable, and nondiscriminatory* market access opportunities for United States persons that rely upon intellectual property protection[.]"[12]

The erroneous decision below undercuts the United States' ability to achieve its international objectives as set forth in the URAA in two respects:

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[8] *See* Testimony of Michael Kantor, U.S. Trade Representative, FDCH Congressional Testimony (Feb. 27, 1996).

[9] H.R. 5110, 103d Cong., 2d Sess., at Title III(B) § 315(1) (1995) *(74a)*.

[10] *Id.* at § 315(2) (emphasis supplied) *(75a)*.

[11] *Id.* at § 315(2)(B) (emphasis supplied) *(75a)*.

[12] *Id.* at § 315(3) (emphasis supplied) *(75a)*.

First, the Federal Circuit's disregard of the clear language of Section 154 creates uncertainty as to how laws passed by Congress to implement international agreements affecting intellectual property will be construed by United States courts. Such uncertainty could cause other countries to hesitate in their own implementation of TRIPs or in entering new agreements with the United States, while others might seek to exploit such uncertainty to advance their own interests.[13]

Second, the decision's radically disparate treatment of patents in force on the effective date of the URAA is completely at odds with the message that the United States must convey to its trading partners as to the United States' own commitment to non-discriminatory patent protection worldwide.

II. The Decision Below Is Contrary To The Express Language of Section 154(c)(1) and Accepted Rules of Statutory Interpretation

There are four fundamental errors in the opinion of the Federal Circuit:

1. The Federal Circuit's decision constitutes an impermissible modification of the express and unequivocal terms of the URAA. Section 154(c)(1) explicitly states that "[t]he *term of patent* that is *in force* on [June 8,

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[13] As a former United States Trade Representative recently testified before Congress: "[T]he United States continues to be embroiled in disputes with other nations in which our interpretation of the TRIPs agreement is being called into question. . . . The United States must continue to be a leader on full implementation of every aspect of the TRIPs agreement. To do otherwise is to jeopardize the long term gains we worked so hard to achieve in the Uruguay Round." Testimony of William Brock, FDCH Congressional Testimony (Feb. 27, 1996).

1995] . . . *shall*" be the greater of the 20-year-from-application or 17-year-from-grant period *(56a)* (emphasis supplied). By granting the benefit, if any, from the new 20-year term to all patents "in force" on June 8, 1995, without exception, Congress signalled its clear intent that all such patents should be treated equally regardless of whether they are "in force" by virtue of a Hatch-Waxman restoration extension or otherwise. The Federal Circuit nonetheless improperly disregarded the plain and absolute language of Section 154(c).[14]

Initially, the court misapplied the word "shall", which mandates that the Congressional directive be given effect. *See Southern Ry. Co. v. Seaboard Allied Milling Corp.*, 442 U.S. 444, 456 (1979). A court may not rewrite legislation to impose an alternative meaning, and thereby completely circumvent the Congressional intent manifested in the statutory language.[15]

Moreover, the Federal Circuit completely ignored the longstanding rule of statutory construction that courts must "presume that Congress is knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). The Federal Circuit

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[14] This Court has consistently maintained that "[i]n a statutory construction case, the beginning point must be the language of the statute, and when the statute speaks with clarity to an issue, judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992).

[15] *See Ardestani v. Immigration and Naturalization Serv.*, 502 U.S. 129, 135 (1991) ("The `strong presumption' that the plain language of the statute expresses congressional intent is rebutted only in `rare and exceptional circumstances' [citation omitted] when a contrary legislative intent is clearly expressed.").

should have recognized that Congress, in enacting the new URAA 20-year patent term, was certainly aware of the renowned Hatch-Waxman Act, such that Congress understood that some patents would be "in force" on June 8, 1995 due to their Hatch-Waxman restorations.

In this case, the Federal Circuit did not even have to presume that Congress was knowledgeable about the Hatch-Waxman Act; instead, Congress clearly demonstrated its awareness of the Hatch-Waxman Act by (i) citing it in the Statement of Administrative Action ("SAA") of the URAA[16] and (ii) specifically amending it through the URAA.[17] Accordingly, the Federal Circuit contravened Congress' mandate that the 20-year term should be provided to all patents "in force" on June 8, 1995, which Congress clearly understood to include patents in force on that date due to their Hatch-Waxman restorations.[18]

Finally, the Federal Circuit has injected an unwarranted statutory disparity into Section 154 by excluding a category of patents in force on June 8, 1995 from receiving the URAA's

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[16] In the SAA, Congress states that "patentees will continue to be able to obtain extensions of patent term for up to five years to compensate for delays caused by pre-marketing regulatory review under the authority of existing section 156 of title 35." Message from the President of the United States, *supra* note 6, at 7, SAA of the URAA at 334 (1994).

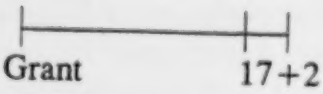
[17] *See* 35 U.S.C. § 156(a)(2) *(56a)*.

[18] Petitioner's interpretation is also consistent with the holdings of the two other Federal Circuit panels faced with the interrelationship between Sections 154 and 156. *See DuPont Merck Phar. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995) and *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130 (Fed. Cir. 1995), *cert. denied*, __ U.S. __, 116 S. Ct. 754 (1996). In both instances, contrary to the panel in the court below, the courts held that the express language of Section 154 must be adhered to when construing the relationship between the two statutes.

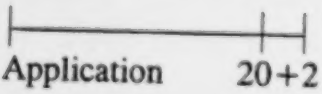
20-year term combined with the two-year Hatch-Waxman restoration extension. As indicated graphically below, the Federal Circuit has created a discriminatory two-tiered system of patent terms with respect to the patents before it, in contradiction of the express terms of the statute:

Discriminatory Effect of the Federal Circuit's Decision

(1) BEFORE URAA:

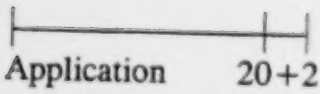


(2) AFTER URAA:



(3) CAFC DECISION:

Patents in force on 6/8/95 due to Hatch-Waxman extensions.



All other patents in force on 6/8/95.

As indicated in the foregoing chart, under the URAA the term of all patents in force on June 8, 1995 is the *greater* of (1) or (2) above. In direct contradiction, the import of the Federal Circuit's decision is that the term of Bracco's patent is the *lesser* of (1) or (2) above.

In essence, the lower court has rewritten Section 154(c) in the following manner (delineated by the underscored section):

> The term of a patent that is in force on or that results from an application filed before June 8, 1995 shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, . . . *unless that patent is in force on June 8, 1995 by reason of a restoration extension pursuant to Section 156, in which event the term of the patent for purposes of Section 156 shall only be 17 years from grant.*

The unequivocal statutory language of Section 154(c) does not support this judicial modification. Indeed, the Federal Circuit's construction of the statute is simply an unauthorized exercise of judicial power.

2. The Federal Circuit's holding violates sound principles of statutory construction by requiring the application of different meanings to the same words closely appearing in the same statutory provision. Through its opinion, the Federal Circuit improperly ascribes two different meanings to the provision "term of patent" as that phrase is used in Sections 154 and 156. Section 154 defines the "term of a patent" *(54a)*. The URAA amended Section 154 to provide patents in force on June 8, 1995 with the recalculated "term of patent" of the longer of 17-year-from-grant or the 20-year-from-application periods *(56a)*. The URAA thereby recalculated pre-June 8, 1995 patent terms for all purposes under the statutory scheme. Accordingly, any and all references to "term of patent" in Section 156 must be read in light of the URAA amendment to the phrase in Section 154.

Contradictory interpretations of identical statutory provisions are clear error. *See Commissioner of Internal*

Revenue v. Lundy, ___ U.S. ___, 116 S. Ct. 647, 655 (1996) ("The interrelationship and close proximity of these provisions of the statute 'presents a classic case for application of the "normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning."')

The Federal Circuit failed to give proper effect to the "term of patent" under Section 156, which became operative by virtue of the URAA, and instead incorporated into Section 156 the superseded "term of patent" provision as it existed prior to the URAA. In doing so, the Federal Circuit has placed the identical provisions of Sections 154 and 156 in direct conflict, a result which should not be countenanced by this Court.

3. The Federal Circuit opinion is internally inconsistent. The PTO took the position below that no patent in force on June 8, 1995 was entitled to have a restoration extension applied to the new 20-year term because Section 156 required that the extension run from the "original expiration date" of the patent *(43a)*. The PTO reasoned that the "original expiration date" could refer only to the 17-year term in effect when the patent issued *(43a-44a)*. In rejecting this argument, the Federal Circuit held that the term of the patent as defined by the URAA in Section 154(c) was controlling for purposes of determining the "original expiration date" of a patent under Section 156 *(15a)*. The court, however, refused to apply the same rationale to patents in force on June 8, 1995 due to a restoration extension, holding instead, as to those patents, that the former 17-year term of patent remained in effect for purposes of Section 156 *(19a)*. Contrary to the court's decision, consistent statutory interpretation dictates that both the "original expiration date" and the restoration extension

must be measured against the recalculated patent term mandated by the URAA.

4. The concerns that led the Federal Circuit to rewrite the statutory language of Section 154(c), namely, that Bracco would receive some form of double Hatch-Waxman extension and that this would lead to a bizarre enforcement scheme *(18a-19a)*, are completely without substance.[19] Section 156(a)(2) states that "the term of a patent . . . shall be extended" under the Hatch-Waxman Act if, *inter alia*, "the term of the patent has never been extended under subsection (e)(1) of this section . . . " *(56a)*. Applying the restoration extension to the new 20-year term would not constitute a second extension to "the term of the patent" as defined in Section 154(c) since the 20-year term had not previously been extended. Nor would there be a cumulative extension under the Hatch-Waxman Act of more than two years. Indeed, the total Hatch-Waxman restoration extension would remain two years.

The Federal Circuit completely failed to recognize that the only increase in patent life that would result from adding the restoration extension to the 20-year term would be the increase in patent life due to the change to the 20-year term under the URAA. As correctly noted by the District Court, this is not a second Hatch-Waxman extension, but merely a change in patent term:

> The court is likewise unpersuaded by the argument . . . that permitting the two year regulatory review extension to be added to the twenty year term for the patents at issue in this case is somehow a

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[19] Even if the concerns were valid, that would not be a sufficient reason to rewrite the language used by Congress. *See Koston v. Secretary*, 974 F.2d 157, 161 (Fed. Cir. 1992).

> second extension which is prohibited by Waxman-Hatch. The only extension which results from adding the two years to the twenty years is the extension applied to the terms of all patents by the URAA.[20]

Undoubtedly, the same patent time should not be double-counted both as a Hatch-Waxman restoration extension and as the recalculated URAA 20-year patent term, as the Federal Circuit held. Moreover, nothing in the language of Sections 154 or 156 or in the legislative history of the URAA suggests that patents in force on June 8, 1995 because of Hatch-Waxman restoration extensions should receive no benefit from the 20-year term. On the contrary, the obvious import of the language of Section 154(c) and its legislative history is that all patents in force on June 8, 1995, as well as all future patents, were to benefit equally from an increase in patent life by reason of the URAA's 20-year term *(56a)*.

Finally, the Federal Circuit's concern that applying a Hatch-Waxman extension to the 20-year term would lead to a "bizarre" enforcement scheme is misplaced because (i) the only patent rights extended during the 20-year term would be those in force on June 8, 1995 with respect to the discrete products covered by the Hatch-Waxman extension and (ii) the remedies available during the period resulting from the new URAA patent term are prescribed in Section 154(c)(2)(B) *(56a)*. Those rights and remedies would be consistently enforceable throughout the 20-year term and the period of the restoration extension. Ironically, the only "bizarre" enforcement scheme is the one created by the Federal Circuit's discriminatory treatment of patents in force on June 8, 1995, contrary to the language and intent of Section 154(c).

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[20] *(27a-28a)*.

* * *

In sum, the Federal Circuit rewrote the clear language of the URAA and violated fundamental rules of statutory construction in order to remedy misplaced concerns. In so doing, it imposed widely disparate treatment on patents in force on the effective date of the URAA contrary to the clear intent of Congress that all such patents receive equal treatment. In both respects, the decision below establishes a precedent that undermines the ability of the United States to achieve the URAA's goal of uniform non-discriminatory protection of intellectual property rights worldwide.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS,
FEDERAL CIRCUIT.

Nos. 96-1068, 96-1105 and 96-1107.

MERCK & CO., INC., and MSD Technology, L.P.,
Plaintiffs-Appellees,

and

Schering Corporation, Plaintiff-Appellee,

and

Bracco Diagnostics Inc. and Bracco International B.V.,
Plaintiffs-Appellees,

and

Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.,
Plaintiffs-Appellees,

and

Organon, Inc., Plaintiff-Appellee,

v.

David A. KESSLER, M.D., Commissioner of Food and Drugs, and Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Defendants-Appellants,

and

Generic Pharmaceutical Industry Association,
Defendant-Appellant.

April 4, 1996.

Holders of drug patents challenged actions of Food and Drug Administration (FDA) and Patent and Trademark Office (PTO), refusing publication of holders' submitted patent expiration dates and seeking declarations that their

patents expired after 20 years, plus previously granted restoration right, and seeking injunctive relief. The United States District Court for the Eastern District of Virginia, Albert V. Bryan, Jr., J., 903 F.Supp. 964, determined that patents were entitled to term of 20 years from filing plus restoration extension. Officials of FDA and PTO appealed. The Court of Appeals, Nies, Senior Circuit Judge, held that (1) case or controversy was adequately presented; (2) PTO's "final determination" ruling on application of Hatch-Waxman Act and Uruguay Round Agreements Act (URAA) was not entitled to deference under *Chevron*; and (3) patent with term of 20 years from filing, pursuant to URAA, could also be extended through restoration extension provided by Hatch-Waxman Act due to delays in FDA approval process, except for those patents kept in force on relevant date for 20-year term calculation only because of previously granted restoration extension.

Affirmed in part, reversed in part, and remanded.

* * * * *

Appealed from: United States District Court for the Eastern District of Virginia (Alexandria); Albert V. Bryan, Jr., Judge.

Harris Weinstein, Covington & Burling, Washington, DC, argued for plaintiffs-appellees, Merck & Co. and MSD Technology, L.P. and plaintiff-appellee, Schering Corporation. With him on the brief were Paul J. Berman and Bruce N. Kuhlik. Also on the brief were John F. Lynch and Nicolas G. Barzoukas, Arnold, White & Durkee, Houston, Texas. Of counsel were Kevin J. McGough, Michael C. Sudol, Jr., Paul D. Matukaitis and Thomas W. Krause.

Donald O. Beers, Arnold & Porter, Washington, DC, argued for plaintiffs-appellees Hoffman-La Roche Inc. and

Syntex (U.S.A.) Inc. With him on the brief was David E. Korn.

Christopher L. Cannon, Vice President, General Counsel, Bracco Diagnostics Inc., Plainsboro, New Jersey, was on the brief for plaintiffs-appellees, Bracco Diagnostics Inc. and Bracco International B.V. Also on the brief were Roger A. Clark, Edward J. Fitzpatrick and George P. Hoare, Jr., Rogers & Wells, Washington, DC.

Wayne H. Matelski, Barbara S. Wahl and Eric B. Bruce, Arent Fox Kintner Plotkin & Kahn, Washington, DC, were on the brief for Plaintiff-appellee, Organon Inc.

John C. Hoyle, Attorney, Department of Justice, Washington, DC, argued for defendant-appellants. With him on the brief were Frank W. Hunger, Assistant Attorney General, Helen F. Fahey, United States Attorney and Douglas N. Letter, Attorney. Also on the brief were Nancy J. Linck, Solicitor, Al Drost, Deputy Solicitor and Scott A. Chambers, Associate Solicitor, Department of Commerce, Patent and Trademark Office, Arlington, Virginia, of counsel.

Alfred B. Engelberg, Greenwich, Connecticut, argued for defendant-appellant. With him on the brief were James F. Flug and Reuben B. Robertson, III, Ingersoll & Bloch, Chartered, Washington, DC.

Donald R. Stone, Gary L. Yingling and Hilda Kay Cross, McKenna & Cuneo, L.L.P., Washington, DC, were on the brief for Amici Curiae, National Pharmaceutical Alliance, Gray Panthers, and United Seniors Health Cooperative.

Cornish F. Hitchcock and Brian Wolfman, Public Citizen Litigation Group, Washington, DC, were on the brief for Amici Curiae, Public Citizen, National Council of Senior Citizens and National Consumers League.

Arthur Y. Tsien and David F. Weeda, Olsson, Frank & Weeda, P.C., Washington, DC, were on the brief for Amicus Curiae, National Association of Pharmaceutical Manufacturers.

Peter T. Cobrin, Cobrin, Gittes & Samuel, New York City, was on the brief for Amicus Curiae, Hovione Sociedade Quimica, S.A.

Robert A. Armitage and Michael A. Sanzo, Vinson & Elkins, L.L.P., Washington, DC, were on the brief for Amicus Curiae, Pharmaceutical Research and Manufacturers of America.

Before ARCHER, Chief Judge, NIES, Senior Circuit Judge, MICHEL, Circuit Judge.

NIES, Senior Circuit Judge.

These appeals raise the question of whether there are limitations to the application of a patent restoration extension, granted pursuant to the Hatch-Waxman Act (35 U.S.C. § 156), to the term of the patent calculated as 20 years from filing under the Uruguay Round Agreements Act (URRA) (35 U.S.C. § 154). The district court held that all patents in force on June 8, 1995, including patents in force only because of a Hatch-Waxman extension, were entitled to add the time of the Hatch-Waxman extension to the new term afforded by the URAA. We affirm-in-part and reverse-in-part.

I.

Two statutes are at issue in this case. The Drug, Price Competition and Patent Term Restoration Act, codified in part at 35 U.S.C. § 156 [1], (also known as the Hatch-

[1] Unless otherwise noted, all citations to the U.S. Code are to the 1988 edition.

Waxman Act), provides generally for a limited extension of the term of a patent, *inter alia,* for a drug as to which marketing was held up during the patent term by the process of obtaining Food and Drug Administration (FDA) approval (hereinafter "restoration extension"). Each of the drug patents in suit received a two-year RESTORATION extension at a time when the term of the patent was 17 years from date of issuance. The second statute is the URAA, 35 U.S.C. § 154 (1995), which provides an alternative calculation of the term for patents in force on June 8, 1995, namely, 20 years from the filing of the patent application. For patents that were prosecuted to issuance in less than three years, URAA effects an extension of its term, that is, the difference between 17 years from issuance and 20 years from filing. Each of the patents in suit was in force on June 8, 1995.

The first of these statutes, the Hatch-Waxman Act, which passed in 1984, eliminated the pre-1984 requirement that a company seeking to market a generic version of a patented drug had to conduct its own testing program. Instead, the Hatch-Waxman Act permits the generic producer of the fully tested drug to rely on the safety and efficacy data of a prior applicant, frequently the holder of a patent on the product. 21 U.S.C. § 355(j)(7)(B); H.R.Rep. No. 857, 98th Cong.2d Sess. Pt. 1, at 16-17 (1984). Thus, the marketing of generic versions of an FDA-approved drug is expedited. In exchange, the Hatch-Waxman Act provides the holders of patents on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining FDA approval. This restoration period does not recover the full time lost from the patent term due to FDA's premarket approval process but merely "ameliorates the loss incurred when patent terms tick away while the patented product is awaiting [FDA's] regulatory approval for marketing." *Unimed, Inc. v. Quigg.* 888 F.2d 826, 829, 12 USPQ2d 1644, 1647 (Fed.Cir.1989). Regardless of the time

so lost, if a patent was issued and testing began before the 1984 enactment of the Hatch-Waxman Act, the total extension period may not exceed two years, 35 U.S.C. § 156 (g)(6)(C); otherwise the restoration period is limited to no more than five years. *Id.* at § 156(g)(6)(B). Further, the effective patent term including the restoration period may not exceed 14 years following FDA approval of the new drug. *Id.* at § 156(c)(3).

Another overall limitation is that the term of the patent may be given only one RESTORATION extension. *Id.* at § 156(a)(2). If the term of the patent has received such an extension, the patent may not be given another restoration extension even for another drug covered by the patent whose marketing also is delayed by reasons of FDA procedures. Finally, the restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based. *Id.* at § 156(b)(1). A restoration extension is made known to the public by the issuance of a certificate by the PTO stating the number of days that the term is extended. *Id.* at § 156(c)(1); 37 C.F.R. § 1.780.

The FDA has major administrative responsibilities under the Hatch-Waxman Act. A generic drug manufacturer is not guilty of infringement by filing an application for approval of marketing (an ANDA) if the generic company does not seek approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent. On the other hand, a patent owner is entitled to notice, and it is an act of infringement for purposes of a declaratory judgment action, for a generic manufacturer to file an ANDA for use prior to the patent expiration date on the basis of alleged invalidity or noninfringement of the patent. The statute requires the FDA to publish the expiration date, and a patent owner must be given notice by the applicant of

an ANDA seeking use before the expiration of the patent.[2]

The second statute, the URAA, was enacted in 1994. The purpose of the URAA was not to extend patent terms, although it has that effect in some cases, but to harmonize the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application. Prior to June 8, 1995, U.S. patents had an expiration date under 35 U.S.C. § 154 measured as 17 years from the date the patent issued, except where terminal disclaimers were filed. Amended section 154(a) now reads:

> Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

35 U.S.C. § 154(a)(2) (1994).

For certain patents which were issued and for pending applications which were filed prior to June 8, 1995, a transitional provision preserves a guaranteed 17-year term, if it is longer than 20 years from filing, by the following provision:

> The term of a patent that is in force on or that results from an application filed before the date that is 6

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[2] A detailed explanation of the workings of the Hatch-Waxman Act is provided by the recent opinion of this court in *Bristol Myers Squibb Co. v. Royce Laboratories, Inc.*, 69 F.3d 1130, 36 USPQ2d 1641 (Fed.Cir.1995), *cert. denied*, ___ U.S. ___, 116 S.Ct. 754, 133 L.Ed.2d 701 (1996).

> months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (1), or 17 years from grant, subject to any terminal disclaimers.

Id. at § 154(c)(1). Patents in the section 154(c)(1) category thus are entitled to keep or to enjoy the 17-year term from issuance of the patent or a 20-year from filing term, whichever is longer.[3]

Congress did not expressly address the question whether a restoration extension under section 156 could be added to the term of a patent which could also invoke the section 154 transition provision. Delineating the combined effects of the URAA and the Hatch-Waxman Act for patents issued prior to June 8, 1995, is thus the task before us.[4] It is agreed that a patent issued after June 8, 1995, on a transition application is entitled to any applicable restoration extension to be added to its term which is 17 years from issuance or 20 years from filing whichever is longer.

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[3] The provisions for extension in section 154 are more complicated than the above-quoted provision alone and include extensions for delay attributable to appellate review. The revised section 154 also includes a limitation on remedies under 35 U.S.C. §§ 283, 284, and 285 against infringers who made a substantial investment before the expiration of the original 17 year term. However, remedies under section 271(c)(4) remain the same. *See Bristol Myers,* 69 F.3d 1130.

[4] The court acknowledges with appreciation the briefs *amici curiae* filed by Public Citizen National Council of Senior Citizens, National Consumers League, National Association of Pharmaceutical Manufacturers, National Pharmaceutical Alliance, Gray Panthers, United States Health Cooperative, Hovione Sociedade Quimica, S.A. and the Pharmaceutical Research and Manufacturers of America.

II.

The plaintiffs in these actions are holders of patents in force on June 8, 1995. When each of the 12 patents in this case was issued, it received a term of 17 years from its grant, pursuant to the then-existing provisions of section 154. Also prior to the URAA's effective date of June 8, 1995, each of these patents receive a two-year restoration extension pursuant to the Hatch-Waxman Act. Five of the patents in issue were "in force" ONLY because the patent term had been given a restoration extension.

On enactment of 35 U.S.C. § 154, these plaintiffs submitted to the FDA requests for publication of new patent expiration dates. As explained above, the FDA is required to publish patent expiration dates in connection with administering the Hatch-Waxman Act. Each of the plaintiff patent holders submitted new expiration dates for their patents based on a term calculated as 20 years from the filing date of the patent application plus two years. The FDA refused to publish the new expiration dates calculated by these patent holders. The basis for the refusal was the issuance by the Commissioner of Patents and Trademarks (the "PTO") of a "Final Determination" which, in effect, ruled that the holder of a patent which was granted before June 8, 1995, was not entitled to have a restoration extension, previously received or one obtained in the future, added to the end of the 20-year term provided under amended section 154.[5]

With respect to patents issued before June 8, 1995, the PTO and FDA took the position that the patentee is entitled to 17 years from issuance plus any restoration extension OR to 20 years from filing (without a restoration add-on), whichever is greater. For each of the patents in suit, the 20-

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[5] 60 Fed.Reg. 30,069 71 (1995).

year from filing term is shorter than the existing term under the PTO interpretation so that the patentee has no claim to a 20-year from filing term. The PTO principally relied on the language in section 156(a) that the term of a patent "shall be extended in accordance with this section from the ORIGINAL EXPIRATION DATE of the patent . . . " (emphasis added). Inasmuch as any patent issued prior to June 8, 1995, was granted a term of 17 years from issuance, the PTO concludes that that date is its "original expiration date" and the restoration extension can only be added thereto. The PTO also notes that, for at least one patent in issue, adding the restoration extension to the 20-year term violates the 14-year cap of section 156(c)(3), absent recalculation. Nothing added to the patent statute by URAA mandates such a RECALCULATION of a restoration extension.

The district court rejected the PTO/FDA interpretation. The district court found that that interpretation would have a disparate impact on those patent applicants whose filing preceded June 8, 1995, and those applicants who filed thereafter. In the court's view, it would be inconsistent with the apparent evenhandedness intended by the URAA to discriminate between these two groups on the basis of filing date of the application. The court rejected the PTO's reliance on the words "original expiration date" in section 156(a), reasoning that the URAA, in effect, changed the "original expiration date" in some cases to mean 20 years from the filing date of the application. As to patents which would have expired prior to June 8, 1995, but for a restoration extension, the court was unpersuaded that permitting a two-year restoration extension to be added anew to a URAA extended term was prohibited under the Hatch-Waxman Act as a "second" extension. The court adhered to this conclusion even where the effective restoration period exceeded the two-year and fourteen-year time limitations for Hatch-Waxman extensions.

III.

A. Jurisdiction

As an initial matter, this court questioned the propriety of reviewing at this time the PTO's "Final Determination" in a declaratory Judgment action. Was the question of its correctness raised in a case or controversy? U.S. Const. art. III, § 2. Upon review of all of the circumstances, we hold that the constitutional limitation on review is satisfied. The dispute arose between appellees and the FDA, which refused to publish new expiration dates pursuant to a claim of entitlement under URAA. In that connection, the PTO's ruling may be reviewed inasmuch as the FDA adopted the PTO's interpretation of the statute as the basis for its action. Further, appellants are damaged by reason of their entitlement to notice from generic manufacturers depending on the patent expiration date which they would not receive without publication of the new date. An actual case or controversy is presented. Cf. *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 35 USPQ2d 1718 (Fed.Cir.1995).

B. Standard of Review

Respecting our view of the merits, we are presented with a matter of pure statutory interpretation. Accordingly, this court reviews the district court's decision on the meaning of the various provisions and their interrelationship *de novo*. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1134, 36 USPQ2d 1641 1645 (Fed.Cir.1995), *cert. denied*, ___ U.S. ___, 116 S.Ct. 754, 133 L.Ed.2d 701 (1966).

Commissioners Kessler and Lehman contend that "under the familiar instructions of the Supreme Court in *Chevron*, 467 U.S. at 844 [104 S.Ct. at 2782-83], PTO's Final Determination is entitled to controlling weight." The con-

tention is unavailing, based as it is on a mistake as to *Chevron's* breadth. Under *Chevron,* where Congress has authorized an agency to promulgate substantive rules under a statute it is charged with administering, we must uphold the agency's interpretation of an ambiguity or omission in that statute if the interpretation is a reasonable one. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842-45, 104 S.Ct. 2778, 2781-83, 81 L.Ed.2d 694 (1984). As the Seventh Circuit recently had occasion to note, however, "only statutory interpretations by agencies WITH RULEMAKING POWERS deserve substantial deference." *Atchison, Topeka and Santa Fe Ry. Co. v. Pena,* 44 F.3d 437, 441 (7th Cir. 1994) (*in banc*) (emphasis added), aff'd, ___ U.S. ___, 116 S.Ct. 595, 133 L.Ed.2d 535 (1996). *See also* 1 KENNETH CULP DAVIS AND RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.3 (1994); Michael Herz, *Deference Running Roit: Separating Interpretation and Lawmaking Under Chevron,* 6 Admin. L.J. Am. U. 187, 200-03 (1992).

As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to "the conduct of proceedings in the [PTO]"; it does NOT grant the Commissioner the authority to issue substantive rules. *Animal Legal Defense Fund v. Quigg,* 932 F.2d 920, 930, 18 USPQ2d 1677, 1686 (Fed.Cir. 1991).[6] Because Congress has not vested the Commissioner with any general substantive rulemaking power, the "Final Determination" at issue in this case cannot possibly have the "force and effect of law." *Chrysler Corp. v. Brown,* 441 U.S. 281, 302, 99

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[6] Accord *Hoechst Aktiengesellschaft v. Quigg,* 917 F.2d 522, 526, 16 USPQ2d 1549, 1552 (Fed.Cir.1990); *Glaxo Operations UK Ltd. v. Quigg,* 894 F.2d 392, 398-99, 13 USPQ2d 1628, 1632-33 (Fed.Cir.1990); *Ethicon Inc. v. Quigg,* 849 F.2d 1422, 1425, 7 USPQ2d 1152, 1154 (Fed.Cir.1988).

S.Ct. 1705, 1718, 60 L.Ed.2d 208 (1979) ("[T]he exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."). Thus, the rule of controlling deference set forth in *Chevron* does not apply. Such deference as we owe to the PTO's interpretative "Final Determination" regarding the interrelationship by the URAA and the Hatch-Waxman Act thus arises, not from the rule of *Chevron,* but solely from, *inter alia,* the thoroughness of its consideration and the validity of its reasoning, *i.e.,* its basic power to persuade if lacking power to control. *See, E.E.O.C. v. Arabian American Oil Co.,* 499 U.S. 244, 257, 111 S.Ct. 1227, 1235, 113 L.Ed.2d 274 (1991); *General Elec. Co. v. Gilbert,* 429 U.S. 125, 140-46, 97 S.Ct. 401, 410-13, 50 L.Ed.2d 343 (1976); *Skidmore v. Swift & Co.,* 323 U.S. 134, 140, 65 S.Ct. 161, 164, 89 L.Ed. 124 (1944).

IV.

MERITS

The PTO/FDA argues that, as a matter of statutory interpretation, no patent issued before June 8, 1995, is entitled to add on any restoration extension to the 20-year from filing term whether the extension was granted before that date or is obtained in the future. With respect to the five patents which were in force only because the restoration period had been added to the 17-year term, the PTO/FDA goes further and argues that reapplication of a restoration period in these instances, as directed by the district court, would violate specific provisions of the statute. Appellant GPIA takes the position that the allowance of an extension for a pre-June 8, 1995, patent depends on when the EXTENSION was granted. Thus, patents issued before June 8, 1995, but which received extensions after that date, would add on that time, but restoration extensions given before June 8, 1995, would attach only to the 17-year from issuance term. The district

court rejected both of these views, ruling that all patents in force on June 8, 1995, are entitled to add a restoration extension to a term calculated as 20 years from filing, regardless of when the extension is granted.

For reasons which follow, we conclude that the pre-June 8, 1995, patents are entitled to add on the restoration extension to a 20-year from filing term regardless of when such extension is granted except for those patents kept in force on June 8, 1995, only because of a restoration extension. Under this interpretation, all provisions of both URAA and Hatch-Waxman can reasonably be given effect. Thus, we affirm-in-part and reverse-in-part.

We disagree with the PTO that the statutory language of section 156(a)(2), *i.e.*, "original expiration date," can mean only the date of expiration when the patent was granted. The legislative history indicates that the phrase "original expiration date" was inserted in association with the limitation that to receive a restoration extension "the term of the patent ha[d] never been extended" BY A PRIOR RESTORATION EXTENSION.[7] Indeed, the only amendment made to Hatch-Waxman by the URAA was to make this explicit. Section

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[7] In June of 1982, Congressman Tom Railsback sent a letter to Mr. Bruce Lehman, then Counsel to the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, detailing technical amendments to H.R. 6444, a 1982 predecessor of the Hatch-Waxman Act. One of the amendments added the language "from the original expiration date of the patent." Regarding this change, Congressman Railsback stated:

> The insertion of "from the original expiration date of the patent" on line 6, makes specific what was intended, namely, that the maximum extension of 7 years [enacted as 5 years] must be calculated from the original expiration date of the patent. Thus 2 five-year regulatory review periods for 2 different products under the same patent will result in only one extension from the original patent expiration date.

156 now reads that a restoration extension may not be given if the patent has been "extended UNDER SUBSECTION (E)(1) OF THIS SECTION" 35 U.S.C. § 156(a)(2) (1994) (emphasis added). Clearly, a patent may receive only one restoration extension. However, we do not agree with the PTO/FDA that this section presents a linguistic barrier to an add-on to a term EXTENDED BY URAA. We conclude that "original expiration date" means no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date.

As evidence of this meaning, it must be noted that 35 U.S.C. § 154(b)(2) provides for a term extension where issuance of a patent is delayed due to appellate review of an adverse determination of patentability. This new type of extension could be determined and granted post-issuance and would be added to the term PRIOR to the addition of a restoration extension which, under section 156(a), is added to the end of what otherwise would be the patent term. Thus, the "original expiration date" of such patent would be its expiration date with the appellate review extension added, *i.e.*, such patent's "original expiration date" would not be the expiration date at the grant of the patent. Nothing in the amendment effecting appellate review extensions suggests otherwise. Thus, we do not find the argument persuasive that, in all instances, the "original expiration date" for a pre-URAA patent must be fixed at 17 years from issuance under section 156(a). The statute, as amended, requires a more flexible interpretation of the phrase "original expiration date." Accordingly, we see no impediment to applying the restoration extension to a 20-year from filing term by reason of this statutory language.

In some instances, there may be a problem in adding a restoration extension granted pre-URAA to the 20-year term. Under the Hatch-Waxman Act the patent term plus any restoration extension cannot exceed 14 years from the

date of FDA approval. 35 U.S.C. § 156(c)(3). With respect to any restoration period GRANTED after June 8, 1995, this 14-year limitation would be part of the calculation of the permissible number of days of the restoration extension. However, the addition of a pre-URAA restoration extension to a post-URAA term might extend past the 14-year limit. Congress has clearly spoken to this point. The 14-year period is a mandatory limit on the extended term and must be given effect. Thus, some pre-June 8, 1995, extensions may need adjustment. GPIA argues for denial of pre-URAA restoration extensions precisely because FDA would have to recalculate the allowable number of days to insure that the 14-year restriction is met. We do not agree with appellants that pre-URAA patentees should be denied restoration extensions for this reason. GPIA's interpretation would treat otherwise equal patents unequally depending upon when the patentee applies for and the FDA grants an extension. Correction to fit within the 14-year limitation entails only a purely ministerial task, no more taxing than the recalculation of a new date for a patent extended by URAA alone (that is, without a restoration extension).[8]

More troubling is the problem of fitting together the different limitations on remedies during successive extensions. For pre-June 8, 1995, patents, a patentee would have full exclusionary rights for 17 years, followed by rights only to equitable renumeration (neither lost profits, an injunction, punitive damages, nor attorney fees) with respect to a certain class of infringers for the period from the end of the 17-year term to the end of the new 20-year term (the delta period),

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[8] The district court did not address the 14-year limitation problem. However, the new expiration date calculated for U.S. Patent No. 4,283,408 exceeds this limit. On remand, the term of this patent must be calculated to expire no later than 14 years after FDA marketing approval.

followed by entitlement to full exclusionary rights but only with respect to the approved product during the period of the restoration extension.

Upon analysis, however, this problem is more illusory than real. Infringers of drug patents who qualify for the relief afforded during the delta period are few and will diminish. The delta period limitation applies only to patents granted before June 8, 1995.[9] Further, the infringing acts, or preparation for such acts, must have begun prior to June 8, 1995, a date which will be increasingly hard to meet. In addition, unlike other manufacturers who may benefit from the delta period, a generic drug manufacturer must obtain FDA approval for marketing its product, now usually by an ANDA. Such a manufacturer is not entitled to go forward with marketing an infringing drug during the delta period without subjecting itself to suit for infringement. *DuPont Merck*, 62 F.3d 1397, 35 USPQ2d 1718. FDA will not approve a generic for marketing under an ANDA where the patentee files suit until the patent has expired, 30 months have passed since the patentee received notice of the ANDA, or the suit is resolved. The length of the delta period can be expected to expire before 30 months. Indeed, in view of the limited time of a delta extension—in all cases substantially less than three years—the problem will be nonexistent in most cases.

If some situations arise where full patent rights are restored for the approved product after an infringer markets a generic drug during a delta period, these can be handled on a case-by-case basis. We conclude that the majority of pat-

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[9] All patents issued after June 8, 1995, are granted with the longer of the two possible terms. No competitor could commit any acts in reliance on an earlier date. Thus, there is no delta period for such patents even though based on an application filed before June 8, 1995.

ents should not be denied extensions because of a mere possibility that special problems may arise in a few instances. The statute contemplates a patentee receiving time lost in its patent term by reason of FDA delay, and the statute should be liberally interpreted to achieve this end.

This leaves for consideration the five patents at issue in this proceeding which were in force on June 8, 1995, only by virtue of having previously received a restoration extension which became operative before that date. With respect to these patents, we must agree with the PTO/FDA position that application of the restoration extension violates specific provisions of the Hatch-Waxman Act and, unlike the 14-year limitation, a minor adjustment does not bring them into conformity. Section 156(a)(2) provides that a restoration extension may be given provided "the term of the patent has never been extended under subsection (e)(1) of this section." The terms of these five patents have once been extended under subsection (e)(1). Indeed, it is only because of actual use of the restoration extension that the patentees can even make their arguments under the Hatch-Waxman Act. A reapplication of the restoration extension would constitute a second extension contrary to the statute.

In addition, Congress has specifically limited any restoration extension for these patents to two years. By first applying the extension to its original 17-year term, and now applying the full extension again to the new term, this limit would be exceeded. For example, U.S. Patent No. 4,001,323 would have expired on January 4, 1994, before enactment of the URAA. It received the maximum extension of two years and had used 17 months of that extension as of June 8, 1995. Under the district court's interpretation, the patentee is entitled to the two-year extension added to a 20-year term. The restoration extension totals 41 months, which exceeds the statutory limit of 24 months. Congress would have had to amend section 156(g)(6)(c) to lift this limitation

for partially used extensions, either to exceed the two-year limit or to allow the time of a restoration extension to be split. No one argues that the statute allows splitting extensions. In any event, Congress made neither change, although, as indicated, it did amend one section of the Hatch-Waxman Act as part the URAA. Thus, we presume it did not intend to lift this ban. This court would simply have to rewrite the statute.

The district court ruled for the patentees on this point because it believed Congress intended that applications filed before URAA should be treated the same as patent applications filed after. However, Congress itself treated these two classes of applications differently. No patent issued on an application filed after June 8, 1995, has a guaranteed 17 year term. With the two-year limitation, Congress struck the balance it wished between restoration extensions and early availability of generics. The two-year limitation, accordingly, cannot be judicially skirted.

Finally, the problem of different remedies is not illusory for these previously extended patents. The restriction of enforcement to one product had already occurred before URAA took effect. To follow this period of limited enforcement with enforcement for all products covered by the patent (or delta enforcement in some cases) and then return to one product enforcement again can only be characterized as bizarre. No principle of statutory construction allows us to ignore specific statutory provisions or adopt an unreasonable construction.

In sum, patents that were in force on June 8, 1995, only because of a Hatch-Waxman extension are not entitled to reapply a restoration extension to a 20-year from filing term. Except for those patents, a patent in force on June 8, 1995, is entitled to have a restoration extension, whenever granted, added to the longer term of either 17 years from issuance or 20 years from filing.

V.

CONCLUSION

For the foregoing reasons we affirm in part, reverse in part, and remand to the district court for amendment of its order in accordance with this opinion.

VI.

COSTS

Each party will bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART AND REMANDED.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1068, -1105, -1107

MERCK & CO., INC., AND MSD TECHNOLOGY, L.P.,
Plaintiffs-Appellees,

and

SCHERING CORPORATION,
Plaintiff-Appellee,

and

BRACCO DIAGNOSTICS INC. AND BRACCO INTERNATIONAL B.V.,
Plaintiffs-Appellees,

and

HOFFMANN-LA ROCHE INC. and SYNTEX (U.S.A.) INC.,
Plaintiffs-Appellees,

and

ORGANON, INC.,
Plaintiff-Appellee,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, and
BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,
Defendants-Appellants,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Defendant-Appellant.

Judgment

ON APPEAL from the UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF VIRGINIA in CASE NOS. 95-CV-1005, 95-CV-1052, 95-CV-1103, 95-CV-1236

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED-IN-PART, REVERSED-IN-PART AND REMANDED

ENTERED BY ORDER OF THE COURT

DATED APR 04 1996

/s/ Francis X. Gindhart
Francis X. Gindhart, Clerk

ISSUED AS A MANDATE: July 19, 1996

APPENDIX B

UNITED STATES DISTRICT COURT,
E.D. Virginia, Alexandria Division.

Civ. A. Nos. 95-1005-A, 95-1052-A, 95-1103-A and 95-1236-A.

MERCK & CO., INC., et al., Plaintiffs,

v.

David A. KESSLER, M.D., Commissioner of Food and Drugs, et al., Defendants.

SCHERING CORPORATION, Plaintiff,

v.

David A. KESSLER, M.D., Commissioner of Food and Drugs, et al., Defendants.

BRACCO DIAGNOSTICS INC., et al., Plaintiffs,

v.

Bruce A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Defendant.

HOFFMANN-La ROCHE INC., et al., Plaintiffs,

v.

Bruce A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Defendants.

Oct. 16, 1995.

Holders of drug patents challenged actions of Food and Drug Administration (FDA) and Patent and Trademark Office (PTO), refusing publication of their submitted patent expiration dates and seeking declarations that their patents expired after 20 years, plus previously granted restoration

right, and injunctive relief. The District Court, Bryan, J., held that extension of restoration rights of patent terms which were allowed under the Hatch-Waxman Act for a time equal to the regulatory review period could be used to extend 20-year patent term established by the Uruguay Round Agreements Act (URAA) as to patents which were in force on URAA's effective date.

Relief granted.

* * * * *

MEMORANDUM OPINION

BRYAN, District Judge.

Effective June 8, 1995, as a result of the enactment of the Uruguay Round Agreements Act (URAA), the terms of patents formerly seventeen years from the date the patent issued, was changed as follows:

> Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

35 U.S.C. § 154(a)(2).

A transitional provision provided as follows:

> The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay

> Round Agreements Act shall be the greater of the 20-year term as provided in *965 subsection (1), or 17 years from grant, subject to any terminal disclaimers.

35 U.S.C. § 154(c)(1).

The issue in these cases is whether extension or restoration rights of patent terms which have been allowed pursuant to 35 U.S.C. § 156 (The Waxman-Hatch Act) for a time equal to the regulatory review period (two years insofar as these cases are concerned) can be used to extend the twenty year period as to patents which are in force on June 8, 1995.[1] In other words, can a holder of a patent in force on June 8, 1995, add a previously granted patent restoration period to a twenty year term in determining when the patent expires.

On June 7, 1995, the Patent and Trademark Office (PTO) published a "Final Determination" which in effect ruled that the holder of such a patent must choose between a term of seventeen years from grant of the patent plus a restoration period, or a term of twenty years from filing without the restoration period.

The Food and Drug Administration (FDA), charged with publication of patent expiration dates submitted by holders of patents in force on June 8, 1995, has refused to publish expiration dates calculated in a manner inconsistent with the ruling of the PTO.

The plaintiffs in these actions are holders of patents in force on June 8, 1995, which have previously been accorded restoration rights and who have been refused publication of their submitted expiration dates by the FDA because of the

---

[1] Some of the patents at issue in these cases had not expired as of June 8, 1995, because the seventeen years had not run, and some of the patents at issue were in force as of June 8, 1995, only because they had previously been granted regulatory review extensions.

PTO ruling. The plaintiffs challenge the actions of the FDA and the PTO and seek declaratory judgments that the actions are unlawful, that their patents expire only after twenty years, plus the previously granted restoration right, and injunctive relief in the form of a direction to the FDA to publish and a withdrawal by the PTO of the Final Determination ruling.

The actions are before the court on the plaintiffs' motions for summary judgment. The government has responded with a motion to dismiss, which is in reality a cross motion for summary judgment. Permitted to intervene and participate in the argument in support of the government's position was the Generic Pharmaceutical Industry Association (GPIA). This is a national trade association whose members include the majority of the manufacturers of generic pharmaceuticals, who obviously have an interest in when patents on pharmaceuticals, the types of patents at issue in this case, expire.

* * * * *

It is conceded that any patent applied for after June 8, 1995, would be for twenty years and would have the benefit of any extension available to it under 35 U.S.C. § 156. The URAA is silent as to the application of regulatory review extensions to the twenty year term. It seems apparent to the court, however, that the URAA's change of the term length was to do no more than bring United States patent law into closer harmony with the laws of other developed nations. Its transitional provision, by providing that the patent term is to apply to previously issued patents, is further indication that no differentiation in restoration rights for patents with the later life was intended. Many statutory enactments draw lines, and some form of prejudice or benefit can accrue depending on which side of the line a party ends up on after the enactment. But the disparate impact on those patent

applicants who precede June 8, 1995, and those who follow, which would result from he [sic] PTO's Final Determination, is inconsistent with the apparent even-handedness intended by the URAA. To draw the inference that the URAA was intended to or did operate to strip from patents in force on June 8, 1995, the carefully drafted regulatory review extensions merely because that act lengthened the patent term from seventeen to twenty years, is not warranted.

The government places its primary argument on the use of the term "original expiration date" as used in The Hatch-Waxman Act. 35 U.S.C. § 156(a), in providing for extensions, is worded as follows:

> The term of a patent which claims a product, a method of using a product, or a ***966** method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if. . . . (Emphasis supplied.)

The government argues that this can only mean the original expiration date from a patent whose term is seventeen years. This is too narrow a construction. The URAA in effect extended the original expiration date to twenty years from the date of application. It effected a change in the "term" as used in § 156(a) and § 156(c).

Nor is the court persuaded by the asserted complicated recalculation involved in the sixty day provision and fourteen year limitation set forth in 35 U.S.C. § 156(d)(1) and § 156(c)(3), respectively.

The court is likewise unpersuaded by the argument, principally made by the intervenor, that permitting the two year regulatory review extension to be added to the twenty year term for the patents at issue in this case is somehow a second extension which is prohibited by Waxman-Hatch. The only extension which results from adding the two years to the

twenty years is the extension applied to the terms of all patents by the URAA. This was no more a windfall to the plaintiffs than the windfall which benefitted many patent holders when the seventeen year term of patents was extended to twenty years.

A substantial portion of the defendants' brief is directed to the deference owed an agency's determination. In the court's view, this is not an issue in the case. Resolution of what the court perceives to be the issues involved here, is a straightforward matter of statutory interpretation.

The declaratory and injunctive relief requested by the plaintiffs will be granted,[2] and the court will declare the eleven patents in issue to have the expiration dates dictated by allowing the previously granted extension to be added to the twenty year term.

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[2] The patents at issue in this action all have had extensions previously granted. Because the rationale of the court's ruling applies to extensions available in the future, the declaratory and injunctive relief applies to patents in force on June 8, 1995, but which may be entitled to extensions in the future.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

CIVIL ACTION NO. 95-1005-A

MERCK & CO., INC., et al.,

Plaintiffs,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, et al.,

Defendants.

CIVIL ACTION NO. 95-1052-A

SCHERING CORPORATION,

Plaintiff,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, et al.,

Defendants.

CIVIL ACTION NO. 95-1103-A

BRACCO DIAGNOSTICS INC., et al.,

Plaintiffs,

v.

BRUCE A. LEHMAN, Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks,

Defendant.

CIVIL ACTION NO. 95-1236-A

HOFFMANN-La ROCHE, INC., et al.,

Plaintiffs,

v.

BRUCE A. LEHMAN, Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks,

Defendant.

[Stamp—SEP 5 1996, Clerk, U.S. District Court, Alexandria, Virginia]

ORDER

This matter is before the court on remand from the United States Court of Appeals for the Federal Circuit. *Merck & Co., Inc. v. Kessler,* 80 F.3d 1543 (Fed. Cir. 1996). The parties have submitted proposed orders carrying out the Federal Circuit's remand. The only disagreement among the parties relates to the provision of paragraph fourteen of plaintiffs' submission. The court concludes that paragraph fourteen should be deleted from the order. The spectre of future litigation outlined by plaintiffs remains just that. Neither this court nor the Federal Circuit has addressed the issue that paragraph fourteen seeks to resolve. The court is unwilling to determine this issue in its amended order. With that deletion, the court has this day entered the proposed amended order submitted by plaintiffs.

/s/ Albert V. Bryan, Jr.
United States District Judge

Alexandria, Virginia
September 5, 1996

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

CIVIL ACTION NO. 95-1005-A

MERCK & CO., INC., et al.,

Plaintiffs,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, et al.,

Defendants.

CIVIL ACTION NO. 95-1052-A

SCHERING CORPORATION,

Plaintiff,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, et al.,

Defendants.

CIVIL ACTION NO. 95-1103-A

BRACCO DIAGNOSTICS INC., et al.,

Plaintiffs,

v.

BRUCE A. LEHMAN, Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks,

Defendant.

CIVIL ACTION NO. 95-1236-A

HOFFMANN-La ROCHE, INC., et al.,

Plaintiffs,

v.

BRUCE A. LEHMAN, Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks,

Defendant.

[Stamp—SEP 5 1996, Clerk, U.S. District Court, Alexandria, Virginia]

~~PROPOSED~~ AMENDED ORDER

Upon consideration of the decision of the United States Court of Appeals for the Federal Circuit affirming in part and reversing in part the judgment entered by this Court on October 16, 1995, it is hereby ADJUDGED, ORDERED and DECLARED that such judgment is modified to provide as follows:

1. These actions are consolidated.

2. The motion of Generic Pharmaceutical Industry Association (GPIA) to intervene is granted.

3. The motions of the plaintiffs in No. 95-1005-A and No. 95-1052-A for summary judgment are granted.

4. The motion of the plaintiffs in No. 95-1236-A for summary judgment is granted as to U.S. Patents No. 4,278,663, No. 4,316,839, and No. 4,355,032 and is denied as to U.S. patents No. 3,985,758, No. 4,078,071, and No. 4,089,969.

5. The motion of the plaintiffs in No. 95-1103-A for summary judgment is denied.

6. The motions of David A. Kessler, M.D., Commissioner of Food and Drug (FDA), and Bruce A. Lehman, Commissioner of Patents and Trademarks (PTO), and the intervenor (together "defendants") to dismiss and for summary judgment in No. 95-1005-A and No. 95-1052-A are denied.

7. The motion of FDA and PTO to dismiss in No. 95-1236-A is granted as to U.S. Patents No. 3,985,758, No. 4,078,071, and No. 4,089,969 and is denied as to U.S. Patents No. 4,278,663, No. 4,316,839, and No. 4,355,032.

8. The motion of FDA and PTO to dismiss in No. 95-1103-A is granted.

9. The Final Determination of the PTO published in the Federal Register at 60 Fed. Reg. 30069 on June 7, 1995, is invalid and unenforceable as to patents in force on June 8, 1995 without application of a patent term restoration period authorized under 35 U.S.C. § 156.

10. The expiration dates for the patents at issue in this action are as follows:

Patent No.	Holder	Exp. Date
4,001,323	Bracco	1/04/96
4,282,233	Schering	6/19/02
4,283,408	Merck	10/15/00
4,146,719	Merck	2/16/00
4,231,938	Merck	6/15/01
4/316,839	Roche	10/10/04
4,278,663	Roche	1/30/03
4,078,071	Syntex	3/07/97
4,089,969	Syntex	5/16/97
4,355,032	Syntex	6/23/03
3,985,758	Syntex	10/12/95

11. For patents entitled to a term of the greater of twenty years from patent filing or seventeen years from grant, under 35 U.S.C. § 154(c)(1), periods of restoration of patent life that have been granted, or that will be granted under 35 U.S.C. § 156, are added to that term, subject to the 14-year limit on effective patent life established under 35 U.S.C. § 156(c)(3), except for patents that were in force on June 8, 1995 only because of a patent term restoration period under 35 U.S.C. § 156.

12. The refusal of the FDA to publish patent expiration dates determined in accordance with this Order is invalid and unlawful.

13. The FDA shall withdraw its Notice declining to publish patent expiration dates determined in accordance with

this Order and shall publish those dates in the "Orange Book" or "Green Book", as appropriate.

~~14. The Final Determination of the PTO, mentioned above, shall be withdrawn by the PTO.~~

15. The FDA is prohibited from approving any abbreviated new drug applications, abbreviated new animal drug applications or applications filed under 21 U.S.C. § 355 (b)(2) that do not take into account the expiration dates of patents as determined by this order.

/s/ Albert V. Bryan, Jr.
United States District Judge

Alexandria, Virginia
September 5th, 1996

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1068,-1105,-1107

MERCK & CO., INC., and MSD TECHNOLOGY, L.P.,
Plaintiffs-Appellees,

and

SCHERING CORPORATION,
Plaintiff-Appellee,

and

BRACCO DIAGNOSTICS INC. AND BRACCO INTERNATIONAL B.V.,
Plaintiffs-Appellees,

and

HOFFMANN-LA ROCHE INC. and SYNTEX (U.S.A.) INC.,
Plaintiffs-Appellees,

and

ORGANON, INC.,
Plaintiff-Appellee,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, and
BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,
Defendants-Appellants,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Defendant-Appellant.

ORDER

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[Filed, U.S. Court of Appeals for the Federal Circuit, JUL 12 1996, Francis X. Gindhart, Clerk]

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by APPELLEE Bracco, and responses thereto having been invited by the court and filed by various other parties, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and responses hving been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on July 19, 1996.

Circuit Judge SCHALL did not participate in the vote.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: July 12, 1996

By /s/ Diane M. Frye
Diane M. Frye
Chief Deputy Clerk

cc: R. ROBERTSON III, J. HOYLE, J. LYNCH, R. CLARK, D. BEERS, H. WEINSTEIN, W. MATELSKI, D. STONE, A. TSIEN, C. HITCHCOCK, P. COBRIN, R. ARMITAGE

MERCK & CO V KESSLER, 96-1068,-1105,-1107
(DCT- 95-CV-1005)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1068,-1105,-1107

MERCK & CO., INC., and MSD TECHNOLOGY, L.P.,
Plaintiffs-Appellees,

and

SCHERING CORPORATION,
Plaintiff-Appellee,

and

BRACCO DIAGNOSTICS INC. and BRACCO INTERNATIONAL B.V.,
Plaintiffs-Appellees,

and

HOFFMANN-LA ROCHE INC. and SYNTEX (U.S.A.) INC.,
Plaintiffs-Appellees,

and

ORGANON, INC.,
Plaintiff-Appellee,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, and
BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,
Defendants-Appellants,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Defendant-Appellant.

ORDER

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

[Filed, U.S. Court of Appeals for the Federal Circuit,
JUL 12 1996, Francis X. Gindhart, Clerk]

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by APPELLEE Organon, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and responses having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on July 19, 1996.

Circuit Judge SCHALL did not participate in the vote.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: July 12, 1996

By /s/ Diane M. Frye
Brian P. LeDuc
Associate Chief Deputy Clerk

cc: REUBEN ROBERTSON III, JOHN HOYLE, JOHN LYNCH, ROGER CLARK, DONALD BEERS, HARRIS WEINSTEIN, WAYNE MATELSKI, STONE, TSIEN, HITCHCOCK, COBRIN, ARMITAGE

MERCK & CO V KESSLER, 96-1068,-1105,-1107
(DCT- 95-CV-1005)

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1068,-1105,-1107

MERCK & CO., INC., and MSD TECHNOLOGY, L.P.,
Plaintiffs-Appellees,

and

SCHERING CORPORATION,
Plaintiff-Appellee,

and

BRACCO DIAGNOSTICS INC. and BRACCO INTERNATIONAL B.V.,
Plaintiffs-Appellees,

and

HOFFMANN-LA ROCHE INC. and SYNTEX (U.S.A.) INC.,
Plaintiffs-Appellees,

and

ORGANON, INC.,
Plaintiff-Appellee,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs, and
BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,
Defendants-Appellants,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Defendant-Appellant.

ORDER

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[Filed, U.S. Court of Appeals for the Federal Circuit, JUL 12 1996, Francis X. Gindhart, Clerk]

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by APPELLANT Kessler, and responses thereto having been invited by the court and filed by various other parties, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and responses having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on July 19, 1996.

Circuit Judge SCHALL did not participate in the vote.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: July 12, 1996

By /s/ Diane M. Frye
Diane M. Frye
Chief Deputy Clerk

cc: R. ROBERTSON III, J. HOYLE, J. LYNCH, R. CLARK, D. BEERS, H. WEINSTEIN, W. MATELSKI, D. STONE, A. TSIEN, C. HITCHCOCK, P. COBRIN, R. ARMITAGE

MERCK & CO V KESSLER, 96-1068,-1105,-1107
(DCT- 95-CV-1005)

APPENDIX E

PTO FINAL DETERMINATION

Patent and Trademark Office

Determination of New Expiration Dates of Certain Patents

AGENCY: Patent and Trademark Office, Commerce.

ACTION: final Determination.

SUMMARY: The Patent and Trademark Office (PTO) has determined the expiration date of patents that:

(1) Are in force on June 8, 1995, and, therefore, are entered to the greater of a term of 20 years from their relevant filing date, or 17 years from grant, and

(2) Have received a term extension under section under section 155 or 156 of title 35, United States Code, or will receive a term extension under section 156 in the future.

All patents falling in this category are entitled to the longer term of either (a) 17 years from grant, supplemented by the period of extension obtained under section 155 or 156, or (b) 20 years from their relevant filing date.

FOR FURTHER INFORMATION CONTACT: H. Dieter Hoinkes, by telephone at (703) 305-9300, by facsimile at (703) 305-8885, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: Under section 156 of title 35, United States Code, patent term extensions are issued for eligible patents from the original expiration date of the patent. Since this provision was enacted in 1984, the PTO has issued 195 certificates of patent term extension in accordance with section 156. Under the Uruguay Round Agreements Act (''URAA''), Public Law 103-465, patents in force on June 8, 1995, are entitled to a patent term of 17

years from grant or 20 years from their earliest filing date, whichever is greater (See 35 U.S.C. 154(c)(1)).

On February 16, 1995, the PTO held a public hearing to elicit comments on what action it should take regarding patents that are entitled to a longer patent term under the URAA and that had previsouly [sic] been extended under section 156. (See 60 FR 3398 (Jan. 17, 1995)). After having considered all the comments, both written and oral, the PTO requested public comments on its intent to publish the new expiration date of all patents that fall into the category mentioned above. (See 60 FR 15748 (March 27, 1995)), using the following three criteria:

(1) A patent that would have expired under the original 17-year patent term before June 8, 1995, but that has received a patent term extension for a period beyond June 8, 1995, is a patent "in force" on June 8, 1995, even though the rights derived from that patent are circumscribed by section 156(b) of title 35.

(2) The "original expiration date of the patent" referred to in section 156(a) of title 35 is the date on which the patent would have expired if it had not been extended under section 156 to expire at a later date. Therefore, the "original expiration date" of the patents under consideration is the date on which the 20-year term from filing expires.

(3) The extension already issued on the basis of the 17-year term is added to the 20-year term, subject to the limitation by imposed by section 156(c)(3) of title 35. That provision limits the period remaining in the term of an extended patent to fourteen years counted from the date on which the product under review received approval for commercial marketing by the relevant regulatory authority.

After analyzing the written comments received regarding the PTO's proposed intent to determine the expiration dates of the relevant patents, taking into account the three criteria

noted above, it has been concluded that criterion (2) is in error and that, therefore, the steps outlined in criterion (3) are not an appropriate course of action. The provisions of section 156 cannot be applied *in vacuo* without obtaining results that could not have been intended by the URAA or that are inconsistent with section 156 itself.

The entire argument in favor of adding an extension obtained under section 156 to a 20-year term obtained under the URAA, was the manner of interpreting the provision in section 156(a), requiring that the term of a patent be extended from its "original expiration date". The term "original expiration date" was proposed to be the date of a patent's expiration without the aid of an extension period, which was proposed to be the end of the 20-year term for those patents entitled to such term.

This narrow interpretation of section 156, however, did not take into account that the term "original" has several meanings, all of which must be taken into consideration to avoid an improper interpretation of the relationship between section 154(c)(1) added to title 35 by the URAA, and section 156, enacted in 1984. To that end, considering the expiration of the longer 20-year term to be *the* original expiration date, ignores the fact that when the patent was issued, it originally had an expiration date of 17 years from grant. That date must continue to be considered "original" for two reasons.

One is, that this was the date on which the patent, when granted, was set to expire. Accordingly, if a patent is now entitled to a longer 20-year term, such is merely an added time period beyond the original expiration date. The other reason is the impossibility of having more than one "original expiration date" without having to refer to one as the first "original" and to the other as the second or new "original", the latter being a contradiction in terms.

Had criteria (2) and (3) been adopted, additional anomalies would have arisen. For example, the term "original

expiration date'' means the date on which a patent would have expired without the extension added by section 156. In the case of many patents in question, their being in force on June 8, 1995, and their entitlement, therefore, to the longer term of 20 years from filing, was solely due to an extension of the original patent term under section 156. In other words, their entitlement to a 20-year term rests on a patent term extension. It is not reasonable, therefore, to ascribe to the end of such 20-year term the appellation ''original expiration'' which under the provisions of section 156(a) was supposed to have been achieved without the aid of an extended term.

Moreover, in cases where the 17-year term expires before June 8, 1995, and the patent is kept in force on that date by virtue of an extension under section 156, transposing such extension to the end of the 20-year term would have resulted in applying at least some of the extended period twice to the term of the patent. This result would have been especially curious in instances where both the original 17 and the 20-year terms expired before June 8, 1995.

Another vexing problem that would have arisen had the PTO proposal been adopted, concerns the question of the rights that a patent holder derives during the period of extension under section 156. If this period had been added to the 20-year term, a patentee would have had full exclusionary rights until the end of the 17-year term, followed by rights only to equitable remuneration with respect to a certain class of infringers during the period from the end of the 17-year term to the end of the 20-year term, and followed by a restoration of full exclusionary rights with respect to the approved product during the continuing period of extension under section 156. A more reasonable solution, such as a continuation of limited patent rights during the period of extension, has no statutory foundation, because section 154(c)(2) added by the URAA does not address extensions under section 156, which itself contains an explicit provision regarding a patentee's rights during the period of extension.

In analyzing section 156(a), it must be remembered that at the time of its enactment in 1984, only one patent term—seventeen years from grant—was available and that all extensions granted under section 156 until now were added to that patent term. Because the URAA does not address the question of patent term extension under section 156, the extensions of all patents issued before June 8, 1995, must continue to be calculated by the PTO on the basis of the 17-year term from grant and added to that term. This is necessitated by the fact that all patents in that category have an original expiration of 17 years from grant, even though they may be entitled to a term of 20 years from filing under the URAA. Further, where the 20-year term from filing exceeds the original term of 17 years from grant, the provisions of the URAA are satisfied in cases where the extension under section 156, added to the 17-year term, expires later than 20 years from the filing date.

All patents in force on June 8, 1995, were originally issued with a term of 17 years from grant. The fact that on June 8, 1995, these patents are entitled to a term of 20 years from filing, if that term exceeds the 17-year term, does not move the original expiration date from which a period of extension continues, if granted under section 156. It only provides a new—albeit not original—expiration date. Accordingly, all patents in this category are entitled either to the 17-year term, as augmented by an extension under section 156, or to a 20-year term from the relevant filing date, whichever is longer. This determination is fully consistent with section 154(c)(1) of title 35, as added by the URAA, because extensions under section 156 are not addressed by section 154(c)(1) and are, therefore, left untouched.

Of course, all patents issued after June 8, 1995, on applications filed before that date, are also entitled to a term that is the greater of 17 years from grant or 20 years from their relevant filing date. Extensions under section 156 granted to these patents must be calculated with reference to whatever

term is applicable at their time of issue and will then be added to that term. As these patents have only one term at issue, there is no question regarding their original expiration date.

Further, under the provisions of section 155 of title 35, 33 patents were extended, each for a length of time to be measured from the date a "stay of regulation of approval was imposed" (December 5, 1975) to the date commercial marketing was permitted (October 22, 1981). This time period amounts to 2,148 days. One of these 33 patents expired in 1992, leaving 32 in force on June 8, 1995.

Section 155 differs from section 156 in providing that "the term of a patent * * * shall be extended * * * by a length of time * * * rather than that the term of a patent shall be extended "from the original expiration date." This difference, however, has no practical effect because the 33 patents that originally were eligible for extension under section 155 already have been extended, as required by that provision. The provisions of section 154(c)(1), therefore, would only have had an effect, if the 20-year term to which 21 patents are entitled, exceeded the 17-year patent term, as extended by 2,148 days. Applying the provisions of section 154(c)(1) to these patents, however, reveals that its requirements are already satisfied, because all previously extended terms exceed a term of 20 years from the patents relevant filing dates. Accordingly, section 154(c)(1) does not benefit any of the patents already extended under section 155.

Comments

Nine written comments were received in response to PTO's request for comments mentioned above. Responses to significant comments follow.

1. Comment: One comment urged that any period of patent term extension used to keep a patent in force on June 8, 1995, not be added to the 20-year term and that only the

portion of the extended patent term past June 8, 1995, be added.

Response: The suggestion has not been adopted because neither section 156 of title 35, nor section 154(c)(1), as added by the URAA, contains a provision that would permit apportioning a term of patent extension in the manner suggested.

2. Comment: Two comments suggested that all patents that received an extension under section 156 prior to June 8, 1995, were extended from an "original expiration date" and that neither the URAA nor section 156 authorizes any alteration. It was suggested, therefore, that any patent in force on June 8, 1995, should expire either at the end of the term extension under section 156 as added to the 17-year term, or at the end of 20 years from filing, whichever is longer.

Response: The suggestion has been adopted for the reasons given above.

3. Comment: Four comments endorsed the PTO's proposal to move the term of extension from the original expiration date of the patent to its new expiration date, although two of the comments took issue with the proposal that the period of extension comply with the limitation proposed by section 156(c)(3).

Response: In light of the fact that the original PTO proposal has not been followed, the question of the applicability of section 156(c)(3) is moot. Nevertheless, it appears anomalous that some supporters of the original PTO proposal would have looked to section 156 for support of transposing the period of extension, while disclaiming the validity of other provisions in section 156 that materially affect that extension.

4. Comment: One comment suggested that the PTO certify the new patent expiration date upon the patentee's request.

Response: The suggestion has not been adopted, as this final determination of the expiration dates of the relevant patents makes certification unnecessary.

It should be noted that any patent in force on June 8, 1995, and any patent issued on the basis of an application filed before June 8, 1995, are entitled to the longer term of 17 years from grant or 20 years from the relevant filing date. Because patents issued before June 8, 1995, were initially given a term of 17 years from grant, any extension under section 156 must begin from the original expiration date, which is the end of the 17-year term. If the term of 20 years from the relevant filing date exceeds the expiration of the extended term, the patent is entitled to such later expiration date. Patents issued after June 8, 1995, on the basis of applications filed before such date, are also entitled to the greater one of the two terms mentioned above. However, as this term attaches at the time of issue, the question of what term is extended under section 156 does not arise.

As the information to determine the applicable expiration dates of all these patents is readily available from relevant patent documents, publication of their expiration dates is not necessary for the purpose of clarification.

Dated: June 1, 1995.

Bruce A. Lehman,
Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 95-13848 Filed 6-2-95; 1:42 pm]

BILLING CODE 3510-16-M

APPENDIX F

FDA RULING

[Docket Nos. 95P-0061, 95S-0117, 95S-0126, and 95S-0135]

Patent Term Expiration Dates for Patents Extended by the Uruguay Round Agreements Act; Submission by Applicants of New Drug and New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its position on patent information submitted by applicants of new drug applications (NDA's) and new animal drug applications (NADA's). Patent term expiration dates for certain patents that are subject to both the Uruguay Round Agreements Act (URAA) and the patent term extension provisions of the United States Code should be calculated in accordance with the Patent and Trademark Office's (PTO's) determination of June 7, 1995. FDA will not publish dates that the NDA or NADA applicant states are not calculated in accordance with the June 7, 1995, determination. This document is intended to advise all NDA and NADA applicants who submitted URAA-extended patent term expiration dates that were not calculated in accordance with the PTO's determination to submit corrected patent term expiration dates to the agency.

DATES: NDA and NADA applicants that submitted inaccurate patent term expiration dates should submit patent term expiration dates calculated in accordance with the PTO's determination by August 21, 1995.

ADDRESSES: Two copies of amended patent information pertaining to human drug products regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by CDER should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CBER should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM-99), Food and Drug Administration, suite 200N, Rockville, MD 20852.

A third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should be sent to the Division of Drug Information Services (HFD-85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 212, Rockville, MD 20852.

Amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV-199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1049.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 1995 (60 FR 30309), FDA announced the availability of the agency's response to a citizen petition from Glaxo, Inc., requesting that FDA explain how the URAA affects the patent information submission and patent

certification requirements for applications to market drug products under the act. In that notice, FDA directed that amended patent information, reflecting extended patent term expiration dates under the URAA, be submitted to FDA between June 8 and July 8, 1995.

On June 7, 1995, the PTO published a notice in the **Federal Register** (60 FR 30069) entitled "Determination of New Expiration Dates of Certain Patents" (the PTO's determination) that established the method for calculating the patent term expiration date for any patent subject to both the terms of the URAA and the patent term extension provisions at 35 U.S.C. 156. FDA has received from several NDA or NADA applicants submissions of new patent term expiration dates which the applicant submitting the information states were not calculated in accordance with the PTO's determination. In order to comply with the requirements of sections 505(b) and 512(b) (21 U.S.C. 360b(b)) of the act and 21 CFR 314.53, NDA and NADA applicants must submit accurate patent information. For the expiration dates for patents that received patent term extension under the URAA to be accurate, those dates must be calculated in accordance with the PTO's determination.

FDA is advising all NDA and NADA applicants who submitted URAA-extended patent term expiration dates that were not calculated in accordance with the PTO's determination to submit corrected patent term expiration dates to the agency by August 21, 1995. If the applicant has already submitted the patent expiration dates that are consistent with the PTO's determination, no additional submission is necessary. FDA will not verify the patent expiration dates submitted by NDA and NADA applicants. FDA will not publish any patent expiration date that the submitter states is not consistent with the PTO's determination.

The agency will publish the new patent term expiration dates submitted during the June 8 to July 8, 1995, period that are not expressly identified by the applicant submitting the information as having been calculated in a manner inconsistent with the PTO's determination. FDA anticipates that the procedures set out in § 314.53(f) will govern with respect to challenges by third parties that the submitted patent term expiration date was not calculated in accordance with the PTO's determination. For these challenges, the procedures set out in § 314.53(f) will be modified so that, if the applicant submitting the challenged patent term expiration date fails to notify FDA within 30 days of receiving notification from the agency of a challenge to the patent that the submitted date is consistent with the PTO's determination, FDA will not continue to publish the challenged date.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CDER should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CBER should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM-99), Food and Drug Administration, suite 200N, Rockville, MD 20852.

To expedite the availability to the public of the updated patent information, a third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Division of Drug Information Services (HFD-85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 212, Rockville, MD 20852.

Amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV-199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Dated: July 18, 1995.

William B. Schultz.
Deputy Commissioner for Policy.

[FR Doc. 95-18079 Filed 7-19-95; 11:00 am]

BILLING CODE 4160-01-F

APPENDIX G

35 U.S.C. § 154. Contents and term of patent

(a) *In General.*—

(1) *Contents.*—Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) *Term.*—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under sections 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(3) *Priority.*—Priority under section 119, 365(a), or 365(b) of this title shall not be taken into account in determining the term of a patent.

(4) *Specification and drawing.*—A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) *Term Extension.*—

(1) *Interference delay or secrecy orders.*—If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section

181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

(2) *Extension for appellate review.*—If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(3) *Limitations.*—The period of extension referred to in paragraph (2)—

(A) shall include any period beginning on the date on which an appeal is filed under section 134 or 141 of this title, or on which an action is commenced under section 145 of this title, and ending on the date of a final decision in favor of the applicant;

(B) shall be reduced by any time attributable to appellate review before the expiration of 3 years from the filing date of the application for patent; and

(C) shall be reduced for the period of time during which the applicant for patent did not act with due diligence, as determined by the Commissioner.

(4) *Length of extension.*—The total duration of all extensions of a patent under this subsection shall not exceed 5 years.

(c) *Continuation.*—

(1) *Determination.*—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) *Remedies.*—The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which—

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) because infringing by reason of paragraph (1).

(3) *Remuneration.*—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

35 U.S.C. § 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review

period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ''approved product''.

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product—

(A) before the expiration of the term of the patent—

(i) under any provision or law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make—

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraphs (1), (4), or (5) of subsection (g).

As used in this subsection, the term ''product'' includes an approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced

so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d) (1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product

and the significant dates applicable to such activities; and

(E) such patent or other information as the Commissioner may require.

(2) (A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B) (i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A),

upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Commissioner of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person

making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term ''due diligence'' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

(5) (A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulatory review and the Federal Statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Commissioner to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Commissioner may require.

(B) If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Commissioner shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall

be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Commissioner of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e) (1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term ''product'' means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term ''drug product'' means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term ''major health or environmental effects test'' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4) (A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507,

512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151-158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1) (A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of—

(i) The period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on

the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

(2) (A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of—

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was

permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3) (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of—

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4) (A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of—

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5) (A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of—

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

> (i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,
>
> (ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or
>
> (iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commerial [sic] marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such para-

graph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

APPENDIX H

103D CONGRESS
2D SESSION

H.R. 5110

IN THE HOUSE OF REPRESENTATIVES

Mr. GEPHARDT (for himself and Mr. MICHEL) (by request) introduced the following bill; which was referred to the Committees on Ways and Means, Agriculture, Education and Labor, Energy and Commerce, Foreign Affairs, Government Operations, Judiciary and Rules.

A BILL

To approve and implement the trade agreements concluded in the Uruguay Round of multilateral trade negotiations.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Uruguay Round Agreements Act".

(b) TABLE OF CONTENTS.—

* * * * *

SEC. 315. OBJECTIVES IN INTELLECTUAL PROPERTY.

It is the objective of the United States—

(1) to accelerate the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15),

(2) to seek enactment and effective implementation by foreign countries of laws to protect and enforce intellectual property rights that supplement and strengthen the standards of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) and the North American Free Trade Agreement and, in particular—

(A) to conclude bilateral and multilateral agreements that create obligations to protect and enforce intellectual property rights that cover new and emerging technologies and new methods of transmission and distribution, and

(B) to prevent or eliminate discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights,

(3) to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection,

(4) to take an active role in the development of the intellectual property regime under the World Trade Organization to ensure that it is consistent with other United States objectives, and

(5) to take an active role in the World Intellectual Property Organization (WIPO) to develop a cooperative and mutually supportive relationship between the World Trade Organization and WIPO.

Supreme Court, U.S.
FILED
NOV 8 1996
CLERK

(2) (2)

Nos. 96-562, 96-575

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1996

ORGANON, INC.,

Petitioner,

v.

DAVID A. KESSLER, M.D., ET AL.,

Respondents.

BRACCO DIAGNOSTICS INC., ET AL.,

Petitioners,

v.

DAVID A. KESSLER, M.D., ET AL.,

Respondents.

On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

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QUESTIONS PRESENTED

The only questions decided adversely to petitioners by the Court of Appeals for the Federal Circuit arise under the Hatch-Waxman Act, 35 U.S.C. § 156, which authorizes patent term restoration for patents covering pharmaceutical products whose marketing has been delayed by the regulatory approval requirements of the Federal Food, Drug, and Cosmetic Act. Those questions are:

1. Would the statutory bar of multiple Hatch-Waxman patent term restoration periods be violated in cases where the patent was in force on June 8, 1995, solely by virtue of a Hatch-Waxman term restoration period if a Hatch-Waxman restoration period is added to the term of 20 years from filing of the patent application that was established by the Uruguay Round Agreements Act ("URAA")?

2. Would the 24-month limitation on certain Hatch-Waxman patent term restoration periods be exceeded

in cases where the patent was in force on June 8, 1995, solely by virtue of the Hatch-Waxman restoration period if a 24-month Hatch-Waxman restoration period is added to the term of 20 years from filing of the patent application that was established by the URAA?

LIST OF PARTIES

This Opposition to Petitions for Writ of Certiorari is filed on behalf of Merck & Co., Inc., MSD Technology, L.P. and Schering Corporation. The parent company, non-wholly owned subsidiaries, and affiliates of Merck & Co. that have issued shares to the public are:

Banyu Pharmaceutical Co., Limited
Banyu ASC Co., Ltd.
Nippon Merck Banyu Co.Ltd.
Prodome Quimica e Farmacaeutica Ltda.
Kronans Droghandel AB
Kiineiesto Oy Irmelinpesa
Comnet Corporation

MSD Technology, L.P. is a limited partnership, comprised of four partners, three of which are wholly-owned subsidiaries of Merck & Co., Inc. The fourth partnership interest in MSD Technology, L.P. is held by Abbey National Treasury Services, P.L.C.

The parent company, non-wholly owned subsidiaries, and affiliates of Schering Corporation that have issued shares to the public are: Schering-Plough Corporation.

Other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.; Organon, Inc.; David A. Kessler, M.D., Commissioner of Food and Drugs; Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks; and the Generic Pharmaceutical Industry Association.

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Nos. 96-562, 96-575

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1996

ORGANON, INC.,
Petitioner,

v.

DAVID A. KESSLER, M.D., ET AL.,
Respondents.

BRACCO DIAGNOSTICS INC., ET AL.,
Petitioners,

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DAVID A. KESSLER, M.D., ET AL.,
Respondents.

On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

---

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

STATUTES INVOLVED

The only statutory issues decided adversely to petitioners by the court below arise under two subsections of the Hatch-Waxman Act, 35 U.S.C. §§ 156(a)(2) and 156(g)(6)(C).

STATEMENT OF THE CASE

The two petitions before the Court originated in five cases brought before the United States District Court for the Eastern District of Virginia to contest the refusal of the Food and Drug Administration ("FDA") to publish patent expiration dates claimed for 12 patents. In each case, the plaintiffs claimed entitlement to add a Hatch-Waxman restoration period to a patent term of 20 years from filing of the patent application that was authorized for patents in force on June 8, 1995, by Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1), as added to the law by the URAA.

In the URAA, Congress eliminated the former patent term of 17 years from grant in favor of a term of 20 years from filing, effective with patents applied for on or after June 8,

1995.[1] A transitional provision requires that the term of each patent in force on June 8, 1995, or that results from an application filed before that date, "shall be the greater" of 17 years from grant or 20 years from filing. 35 U.S.C. § 154(c)(1). Apart from one amendment to Section 156(a)(2), Congress left unchanged the provisions of the Hatch-Waxman Act that add restoration periods[2] to the terms of patents covering products, such as drugs, subject to pre-market regulatory delay by the FDA.[3] *See generally Bristol-Myers*

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[1] 35 U.S.C. § 154(a)(2), Pub. L. 103-465, Title V, §§ 532(a)(1), 534.

[2] The period of Hatch-Waxman patent term restoration does not recover the full time lost to the FDA's pre-market approval process, but merely "ameliorate[s] the loss incurred when patent terms tick away while the patented product is awaiting regulatory approval for marketing" by the FDA. *Unimed, Inc.* v. *Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1647 (Fed. Cir. 1989). Because a considerable part of the effective life of a patent can be consumed by the FDA regulatory processes, the Hatch-Waxman Act provides holders of pharmaceutical patents with term restoration to "reward a patentee for research and development efforts by extending the life of a patent covering an innovative new drug whose marketing was delayed by FDA regulatory review." *Glaxo Operations U.K. Ltd.* v. *Quigg*, 706 F. Supp. 1224, 1229 (E.D. Va. 1989), *aff'd*, 894 F.2d 392, 13 U.S.P.Q.2d (BNA) 1628 (Fed. Cir. 1990).

[3] If the patent was issued and human testing began before the 1984 enactment of the Hatch-Waxman Act, the maximum permitted restoration period is two years. Otherwise, the restoration period is in most cases

(continued...)

Squibb Co. v. *Royce Laboratories*, 69 F.3d 1130, 1136-37, 36 U.S.P.Q.2d (BNA) 1641, 1647-48 (Fed. Cir. 1995), *cert. denied*, ___ U.S. ____, 116 S.Ct. 754 (1996); *DuPont Merck Phar. Co.* v. *Bristol-Myers Squibb Co.*, 62 F.3d 1396, 1402, 35 U.S.P.Q.2d (BNA) 1718 (Fed. Cir. 1995). The sole URAA amendment to Section 156(a)(2) provides that only a prior Hatch-Waxman patent term restoration period disqualifies a patent from further term restoration under Hatch-Waxman. *See* 35 U.S.C. § 156(a)(2).

The district court ruled for all the plaintiffs as to all 12 patents. The Court of Appeals for the Federal Circuit thereafter reversed the determination of the district court as to

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[2/](...continued)
limited to five years. 35 U.S.C. § 156(g)(6)(C); *Cf. Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522, 16 U.S.P.Q.2d (BNA) 1549 (Fed. Cir. 1990). All patents in suit other than petitioner Organon's U.S. Patent No. 3,927,046 (the "'046 patent') are subject to the two-year limitation on patent term restoration.

For all patents receiving Hatch-Waxman term restoration, the effective patent life, including the patent term restoration period, may not exceed 14 years following FDA approval of the product for commercial marketing. 35 U.S.C. § 156(e)(3).

five of the patents. Petitioners Bracco and Organon each hold one of the five patents adversely affected by the decision below. The other three are held by respondents Hoffmann-La Roche and Syntex (together "Roche"), which have not sought review in this Court. Each of these five patents was in force on June 8, 1995, solely by virtue of a Hatch-Waxman restoration period, as the pre-URAA term of 17 years from grant had ended prior to June 8, 1995. No more than three dozen additional patents are in similar circumstances.[4/]

Respondents Merck and Roche each hold three and respondent Schering holds one of the other seven patents in suit. The district court ruling was affirmed below as to each of these seven patents.

The Federal Circuit held in its decision of April 4, 1996, that holders of pharmaceutical patents may add a patent term

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[4/] The decision complained of in the petition can affect only patents satisfying two criteria: the patent was in force on June 8, 1995 solely by virtue of a previously authorized Hatch-Waxman patent term restoration period, and the patent was granted less than three years after the patent application was filed. Publicly available data show approximately forty patents that satisfy these criteria.

restoration period previously certified under the Hatch-Waxman Act to the term of 20 years from filing established by Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1), as added by the URAA, subject only to specific limitations established in the Hatch-Waxman Act itself. On the basis of two of those limitations, the court below held that patents whose pre-URAA 17-year term had expired prior to June 8, 1995 and were "in force on June 8, 1995, only because of a restoration extension" are not eligible for a 20-years-from-filing term plus a Hatch-Waxman restoration period. *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). (96-562 Pet. App. 15a).[5/]

[5/] In accordance with petitioners' contentions below, the Federal Circuit concluded that under Section 154(c)(1) "pre-June 8, 1995, patents are entitled to add on the restoration extension to a 20-year from filing term regardless of when such extension is granted . . . ." *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). (96-562 Pet. App. 15a). Accordingly, petitioners may seek review only of that part of the ruling that identified an exception for patents such as Bracco's U.S. Patent No. 4,001,323 (the "'323 patent") and Organon's '046 patent that would have expired prior to June 8, 1995 in the absence of Hatch-Waxman term restoration. *Id.*

The Federal Circuit based the latter result on two statutory sections that limit the availability of Hatch-Waxman Act patent term restoration periods. First, the Federal Circuit relied on Section 156(a)(2) of the Hatch-Waxman Act, which limits Hatch-Waxman patent term restoration to cases where "the term of the patent has never been extended" under the Hatch-Waxman Act. The court reasoned:

> The terms of these five patents have once been extended under [Hatch-Waxman] . . . . A reapplication of the restoration extension would constitute a second extension contrary to the statute.

Id. at 1552. (96-562 Pet. App. 21a).

Second, the Federal Circuit concluded that because part of the Hatch-Waxman restoration period had run prior to June 8, 1995, addition of the full 24-month restoration period of petitioner Bracco's '323 patent to the 20-years-from-filing term of Section 154(c)(1) would violate the 24-month limitation that Section 156(g)(6)(C) places on term restoration for that patent. The court below held:

> For example, U.S. Patent No. 4,001,323 would have expired on January 4, 1994, before enactment of the URAA. It received the maximum [Hatch-Waxman] extension of two years and had used 17 months of that extension as of June 8, 1995. Under the district court's interpretation, the patentee is entitled to the two-year extension added to a 20-year term. The restoration extension totals 41 months which exceeds the statutory limit of 24-months.

Id.

REASONS FOR DENYING THE WRIT

No issue of general importance is raised in these cases, there is no conflict with any Supreme Court decision, and there is not and never will be a conflict of decisions among the courts of appeals. The Federal Circuit's decision adverse to petitioners turns on a narrow issue of statutory construction that affects no more than a handful of patents and even that small number is dwindling with time. The petitions therefore present no issue worthy of this Court's review.

1. The Federal Circuit's decision adverse to petitioners affects only those pharmaceutical patents that were in force on

June 8, 1995 solely by virtue of a Hatch-Waxman patent term restoration period. Only a small number of patents could ever have fallen into this category and therefore could have been affected by the decision below.[6/] Moreover, the number of patents whose terms would be affected by a decision of these issues by this Court becomes smaller with the passage of time. Already, a number of those patents would have expired even under the legal theory petitioners advance.[7/]

To secure review by this Court in the absence of a conflict among circuits, petitioners must demonstrate both that there is a substantial basis for believing the court below erred in its construction of the governing statute and that the issue has substantial importance. *See* Sup. Ct. R. 10(c) (among the considerations governing review on certiorari is when "a federal court of appeals has decided an important question of

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[6/] *See* n. 4 *supra*.

[7/] An example is provided by petitioner Organon's '046 patent, which would have expired on November 6, 1996, under petitioners' legal theory. *See* pp. 14-15 *infra*.

federal law which has not been, but should be, settled by this Court . . ."). This showing is one petitioners cannot make, and they therefore do not meet the demanding standards that govern the issuance of a writ of certiorari.[8/]

2. The decision of the Federal Circuit does not conflict with any decision of this Court or any other court of appeals. Nor could there ever be such a conflict among the circuits, as the issues presented are within the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. § 1295(a)(1).

3. Petitioners are incorrect in contending that the Federal Circuit's decision re-writes the language of Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1). (See 96-575 Pet. at 12 and 14; and 96-562 Pet. at 8-9). As the

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[8/] The lack of importance of the issues decided below is further shown by the decision of the Solicitor General not to seek review of the parts of the Federal Circuit's decision that were adverse to the Government's contentions. Similar decisions were made by respondent Generic Pharmaceutical Industry Association, a trade association of generic pharmaceutical manufacturers, which vigorously supported the Government's position below, and by Roche, which is the owner of three of the five patents whose terms were adversely affected by the aspects of the Federal Circuit's decision of which petitioners complain.

Federal Circuit's opinion recognized, Section 154(c)(1) is "a transitional provision" that permits every patent whose term was "in force" on June 8, 1995 "to enjoy the 17-year term from issuance of the patent or a 20-year from filing term, whichever is longer." *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1547-48 (1996). (96-562 Pet. App. 15a).

The Federal Circuit's reversal of the favorable judgment that petitioners secured in the district court focused not on Section 154(c)(1), but upon two subsections that the Hatch-Waxman Act incorporated in Section 156 of the Patent Act, 35 U.S.C. § 156. Under that court's analysis, the dispositive fact in petitioners' cases was that their patents were in force on June 8, 1995, only because the Hatch-Waxman restoration periods of those patents had come into operation prior to June 8, 1995.

In relying upon Section 156(a)(2), which "provides that a [Hatch-Waxman] restoration extension may be given provided 'the term of the patent has never been extended under

subsection (e)(1) of this section,'" the court cited the fact that petitioners' patents already had "once been extended under subsection (e)(1)" prior to the June 8, 1995, effective date of the URAA. *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1552 (Fed. Cir. 1996). (96-562 Pet. App. 21a). The decision concludes that "re-application of the restoration extension" at the end of the 20-year term "would constitute a second extension contrary to the statute." *Id.*

In alternatively relying upon Section 156(g)(6)(C), which limits the length of any Hatch-Waxman restoration of the terms of patents such as Bracco's '323 patent to two years, the court below concluded that addition of the Hatch-Waxman extension to the URAA term of 20 years from filing would result in a Hatch-Waxman term restoration extension exceeding "the statutory limit of 24 months" imposed by Section 156(g)(6)(C). *Id.*

The Federal Circuit fully sustained petitioners' contentions on every other issue, including the interpretation of other

relevant parts of the Hatch-Waxman Act and Section 154(c), as added by the URAA. Thus, the Federal Circuit held that all patents in suit, including those of petitioners Bracco and Organon, were "in force on June 8, 1995." *Id.* at 1548. (96-562 Pet. App. 9a). The Federal Circuit further sustained petitioners' contention that the phrase "original expiration date" in Section 156(a) "means no more than that the expiration date has not been extended under section 156(e)(1)" of the Hatch-Waxman Act. *Id.* at 1551. (96-562 Pet. App. at 15a). Accordingly, no issue under the URAA was resolved adversely to petitioners' contentions and, therefore, they have no such issue to raise before this Court.

4. Petitioner Organon does not present an issue available for review on certiorari in its argument that the FDA in effect modified its own regulations in violation of the Administrative Procedure Act ("APA") when it refused to publish patent expiration dates tendered by petitioners. (96-562 Pet. App. at 12-20). While respondents Merck and Schering agree that the

FDA's action was at odds with its own regulation governing publication of patent expiration dates claimed by holders of pharmaceutical patents, *see* 21 C.F.R. § 314.53(e) (1995) (96-562 Pet. App. 195a), the violation was not approved by the Federal Circuit. Indeed the Federal Circuit's ruling in favor of respondents Merck and Schering necessarily overrules the FDA's action and the Federal Circuit did not in any fashion rely upon the FDA regulation in ruling against petitioners. Therefore, the APA issue is not fairly presented for further review.

5. Organon's petition should be denied for the further reason that it is moot. Under the Federal Circuit's decision, Organon's '046 patent expired nearly a year ago, on November 19, 1995. Under the statutory theory that Organon advanced below and argues in its petition for certiorari, the life of the patent would be extended only to November 6, 1996. Since the latter date has come and gone, any grant of a writ of certiorari and subsequent proceedings on the merits

of the case would occur only after the patent expiration date for which Organon contends. Furthermore, Organon does not claim to have rights to any other patent that would be affected by further review of the Federal Circuit's decision. As a result, Organon's case has become moot. *See Lewis* v. *Continental Bank Corp.*, 494 U.S. 472, 477-78 (1990) (Supreme Court jurisdiction dependent on continued interest of parties in outcome of case); *Deakins* v. *Monoghan*, 484 U.S. 193, 199 (1988) (Article III jurisdiction limited to "actual ongoing controversies").

CONCLUSION

The petition for a writ of certiorari should be denied.

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November 8, 1996

(3) (3)

Nos. 96-562 and 96-575

Supreme Court, U.S.
FILED
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In the Supreme Court of the United States

OCTOBER TERM, 1996

ORGANON, INC., PETITIONER

v.

DAVID A. KESSLER,
COMMISSIONER OF FOOD AND DRUGS, ET AL.

BRACCO DIAGNOSTICS INC. AND
BRACCO INTERNATIONAL B.V., PETITIONERS

v.

DAVID A. KESSLER,
COMMISSIONER OF FOOD AND DRUGS, ET AL.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

The 1994 Uruguay Round Agreements Act (URAA) establishes a new patent term of 20 years from the date on which the patent application was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA provides that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in subsection (a) or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1).

1. The petitions in Nos. 96-562 and 96-575 present the question whether the requirement of the Hatch-Waxman Act, 35 U.S.C. 156(a)(2), that, in order to receive a Hatch-Waxman Act extension, a patent must not have been previously extended under Section 156(e)(1) of that Act, precludes adding such extension to the URAA's new 20-year term for patents that were in force on the effective date of the URAA solely because the patent's original 17-year term had been extended pursuant to Section 156(e)(1).

2. An additional question presented by the petition in No. 96-562 is whether the Food and Drug Administration (FDA) violated the Administrative Procedure Act (APA), 5 U.S.C. 553, by publishing a notice, without prior notice and comment, stating that FDA would not publish patent expiration dates submitted by applicants for new drug applications and new animal drug applications if the submitter stated that the expiration dates were not calculated in accordance with the Patent and Trademark Office's (PTO) Final Determination regarding whether an extension under the Hatch-Waxman Act could be added to the URAA's newly created 20-year patent term.

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In the Supreme Court of the United States

OCTOBER TERM, 1996

No. 96-562

ORGANON, INC., PETITIONER

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DAVID A. KESSLER,
COMMISSIONER OF FOOD AND DRUGS, ET AL.

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v.

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ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a)[1] is reported at 80 F.3d 1543. The opinion of the

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[1] Unless otherwise indicated, Pet. App. refers to the Appendix in No. 96-562.

district court in No. 96-575 (Pet. App. 28a-39a) is reported at 903 F. Supp. 964. The opinion of the district court in No. 96-562 (Pet. App. 24a-27a) is unreported. The district court's orders on remand from the court of appeals' decision (Pet. App. 40a-41a; 96-575 Pet. App. 29a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 92a-94a) was entered on April 4, 1996, and its mandate was issued on July 19, 1996. Petitions for rehearing were denied on July 12, 1996. Pet. App. 80a-91a. The petition for a writ of certiorari in No. 96-562 was filed on October 9, 1996, and the petition for a writ of certiorari in No. 96-575 was filed on October 10, 1996. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Prior to the enactment of the Hatch-Waxman Act and the URAA, a patent for an innovator or pioneer drug was in force for a term of 17 years from the date that the patent was issued. 35 U.S.C. 154 (1988). In 1984, Congress enacted the Hatch-Waxman Act, which incorporates the patent status of a drug, or the use of a drug, into the drug approval process, and permits certain drug patents to be extended (or restored) "from the original expiration date of the patent." 35 U.S.C. 156(a). The Section 156 extension restores some of the time spent obtaining the required pre-marketing approval from the Food and Drug Administration (FDA). See 35 U.S.C. 156(c) and (g); H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, 40-41 (1984). The length of the extension varies according to several factors, but if the patent was issued and human testing began before enactment of

the Hatch-Waxman Act in 1984, the total extension may not exceed two years; otherwise the restoration period generally is limited to five years. 35 U.S.C. 156; Pet. App. 4a-5a. The extension may be granted only if the patent has not been extended under Section 156(e)(1). 35 U.S.C. 156(a)(2). In addition, the extension may not extend the effective life of the patent more than 14 years following FDA approval of the New Drug Application (NDA). 35 U.S.C. 156(c)(3).

2. Effective June 8, 1995, the URAA establishes a new patent term of 20 years from the date on which the application for the patent was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA states that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in [the URAA] or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1). The URAA does not address how Hatch-Waxman extensions under Section 156 are to be applied during the transition period.

After notice and comment, PTO published on June 7, 1995, its "Final Determination" to resolve how it would apply Section 156 extensions to patents covered by Section 154's transitional provision. Pet. App. 56a-66a. Relying on the statutory language of the Hatch-Waxman Act that provides that the extension runs "from the original expiration date of the patent," 35 U.S.C. 156(a), PTO determined that with respect to patents that were in force on or resulted from applications filed before June 8, 1995, Hatch-Waxman extensions could be added only to the original term of 17 years from the date of the patent's issuance, not the new 20-year term. Thus, under PTO's ruling, holders of patents of innovator or pioneer drugs covered by

the transitional provision of the URAA, 35 U.S.C. 154(c)(1), were entitled to the greater of the 17-year term plus the Hatch-Waxman extension, or a term of 20 years from the date the patent application was filed.

3. Companies seeking to market pioneer or innovator drugs must first obtain FDA approval through the filing of a New Drug Application. 21 U.S.C. 355. In addition to submitting to FDA data that demonstrate the safety and effectiveness of the drug, the Hatch-Waxman Act requires applicants to provide the FDA with "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). FDA publishes this information in its *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). 21 C.F.R. 314.53(e).

A manufacturer who wishes to market a generic version of a pioneer drug must submit to FDA an Abbreviated New Drug Application (ANDA). 21 U.S.C. 355(a) and (j). The ANDA must contain, among other things, a certification with respect to each patent that claims the drug or method of the drug's use. 21 U.S.C. 355(j)(2)(A)(vii).[2] A certifica-

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[2] The certification must state one of the following:

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) * * * the date on which such patent will expire, or

tion that the applicable patent is invalid or will not be infringed (see note 2, *supra*) requires that the ANDA applicant give notice of the ANDA filing to the patent owner and the NDA holder for the listed drug.[3] FDA may approve an ANDA with such a certification, effective immediately, despite the unexpired patent, unless an action for infringement is brought against the ANDA applicant within 45 days of receipt of the certification. 21 U.S.C. 355(j)(4)(B)(iii). If an infringement action is brought, approval of the ANDA will not become effective until 30 months from receipt of the certification notice, unless the infringement case is decided sooner or the court shortens or extends the period. 21 U.S.C. 355(j)(4)(B)(iii).

On June 8, 1995, FDA issued a notice which, while not stating a position on the patent law question involved in this case, required that NDA holders submit new patent term expiration dates if the patent term was affected by the URAA. Pet. App. 67a-73a. FDA also requested that ANDA applicants amend any pending applications to respond to any URAA-affected dates submitted by NDA holders. *Id.* at 71a-72a. In response to this notice, FDA received a number of submissions that stated that the patent expiration dates were not calculated in accordance with PTO's Final Determination, but instead were

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> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. 355(j)(2)(A)(vii).

[3] This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. 21 U.S.C. 355(j)(2)(B).

calculated by adding the Hatch-Waxman extension period to the 20-year term created by the URAA. *Id.* at 76a-77a. On July 21, 1995, FDA published a notice stating that it would not publish patent expiration dates which the submitter stated were not calculated in accordance with PTO's Final Determination. *Id.* at 74a-79a.[4] Accordingly, FDA refused to publish the holders' newly calculated expiration dates.

4. Holders of patents for pioneer or innovator drugs in force on June 8, 1995 brought suits challenging the actions of PTO and FDA. Four cases, including that of the petitioner in No. 96-575, were consolidated by order of the district court. C.A. App. 8-11.[5] The district court held that holders of patents in force on the effective date of the URAA were entitled to have the Hatch-Waxman extension period added to the URAA's newly created 20-year term. Pet. App. 28a-39a. The court declined to defer to PTO's Final

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[4] The notice also requested submission of amended patent expiration dates within 30 days of the notice. Pet. App. 74a-75a, 77a. The notice further stated that FDA would publish dates that were not expressly identified by the submitter as inconsistent with PTO's determination, and would rely on the challenge procedures of 21 C.F.R. 314.53(f) to identify incorrectly calculated dates. Pet. App. 74a, 77a. In the event of a challenge, FDA would forward the challenge to the NDA applicant and request confirmation that the expiration dates were calculated in accordance with PTO's determination. The notice also stated that, if the applicant submitting the challenged information did not submit a confirmation or corrected date, FDA would not publish the challenged date. *Id.* at 77a-78a.

[5] Those four cases are *Merck & Co., Inc., et al.* v. *Kessler, et al.*, No. 95-1005-A; *Schering Corp.* v. *Kessler, et al.*, No. 95-1052-A; *Bracco Diagnostics Inc., et al.* v. *Lehman*, No. 95-1103-A; *Hoffmann-LaRoche Inc., et al.* v. *Lehman*, No. 95-1236-A (E.D. Va.).

Determination in a "straightforward matter of statutory interpretation." *Id.* at 34a. The court noted that it was undisputed that "any patent applied for after June 8, 1995, would be for twenty years and would have the benefit of any extension available to it under 35 U.S.C. § 156." *Id.* at 32a. The court concluded that URAA's transition provision did not indicate a congressional intent to differentiate between those post-June 8, 1995 patents and patents covered by Section 154's transitional provision. Pet. App. 32a-33a. Accordingly, the court granted plaintiffs' motion for summary judgment, and entered an order (1) declaring PTO's Final Determination "invalid and unenforceable"; (2) declaring the expiration dates of the 11 patents at issue to be the dates submitted by the patent holders, *i.e.*, the URAA's 20-year period plus the Hatch-Waxman restoration period; (3) requiring FDA to publish those expiration dates in the Orange Book; and (4) prohibiting FDA from approving any applications that did not take into account the expiration dates required by the court's order. Pet. App. 38a-39a.

Less than a month after its decision in the four consolidated cases, the district court entered a memorandum opinion and order that granted petitioner in No. 96-562 "the same injunctive and declaratory relief" accorded to plaintiffs in the consolidated cases "for the same reasons set forth" in those consolidated cases. Pet. App. 24a.

5. The federal defendants appealed the four consolidated cases and petitioner Organon's case, all of which were consolidated on appeal. The court of appeals affirmed in part and reversed in part. Pet. App. 1a-23a.

The court decided the statutory interpretation question *de novo*, refusing to accord deference to PTO's Final Determination because PTO did not have substantive rulemaking authority. Pet. App. 12a-14a.[6] Further, the court rejected PTO's construction of the statutory phrase "original expiration date" in Section 156 as describing the expiration date of the original 17-year term that the patent received upon issuance, and, accordingly, PTO's conclusion that a Hatch-Waxman extension under Section 156 could be added only to the expiration of the original term of 17 years from issuance. Pet. App. 15a-16a. Instead, the court reasoned that the phrase "'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date." *Id.* at 17a. The court determined that, for most patents covered by the URAA's transitional provision, the Hatch-Waxman extension would be added to the newly created 20-year-from-application term, if that result yielded a greater term than adding the extension to the previously existing 17-year-from-issuance term. *Id.* at 14a-20a.

The court concluded, however, that the Hatch-Waxman Act precluded the addition of the Hatch-Waxman extension to the URAA's newly created 20-year term for petitioners' patents. Pet. App. 20a-23a. Because petitioners' patents would have expired prior to the effective date of the URAA but for the fact that they were extended under Section 156, the court concluded

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[6] Because of the court's failure to give deference to PTO's interpretation of Sections 154 and 156, the federal parties have filed a conditional cross-petition simultaneously with the filing of this opposition.

that adding a Section 156 extension to the new 20-year term would constitute a second extension under Section 156 and would exceed the statutory limits of Section 156. Pet. App. 23a.

Petitioners and the federal parties filed petitions for rehearing, which the court of appeals denied. Pet. App. 80a-91a.

ARGUMENT

This case does not present an issue of public importance warranting review by this Court.

1. The statutory provision at issue is a transitional provision of only a temporally limited significance. Under the theory advanced by petitioners, the term of the patent in No. 96-562 expired on November 6, 1996 (Pet. App. 24a), a fact that appears to render that case moot.[7] The term of the patent in No. 96-575 expires on November 24, 1997. 96-575 Pet. 4. We also are informed that, to PTO's knowledge, a maximum of 41 patents, including petitioners' patents, were in force on the effective date of the URAA solely because they were extended under Section 156. Petitioners argue only that the decision of the court of appeals is wrongly decided. They suggest no reason—and we know of none—why this case involves an issue of substantial and continuing importance to the public warranting this Court's review. See *Rice* v. *Sioux City Memorial Park Cemetery*, 349 U.S. 70,

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[7] To our knowledge, no drug was approved for marketing by the FDA during the period of the patent that could result in an infringement suit. Petitioner in No. 96-562 has not suggested any other situation that would present a live controversy.

79 (1955); *Layne & Bowler Corp.* v. *Western Well Works, Inc.*, 261 U.S. 387, 393 (1923).[8]

2. In addition, the patent law arguments presented by petitioners lack merit.[9] Petitioners argue (96-562 Pet. 8-9; 96-575 Pet. 8-16) that the court of appeals' decision deprives their patents of the mandatory benefit of the 20-year term provided by the transitional provision of the URAA, 35 U.S.C. 154(c)(1). That is not correct. Petitioners' patents unquestionably receive the greater of the URAA's newly created 20-year-from-application term or their original 17-year-from-issuance term. The question presented, however, is whether transitional patents are entitled to a Hatch-Waxman extension in addition to the URAA's 20-year term when a Hatch-Waxman extension had already been granted to the patent and had at least partially expired before the effective date of the URAA. The statutory provisions at issue do not expressly answer that question. Contrary to petitioners' argument, the court of appeals correctly ruled that the provision of the Hatch-Waxman Act, 35

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[8] Although petitioners suggest (96-562 Pet. 5-6; 96-575 Pet. 6-8) that the court of appeals' decision has international ramifications, neither petition provides substantiation for that suggestion, which is implausible in light of the temporary nature of the questions presented.

[9] As we explain in our conditional cross-petition filed simultaneously with this response, PTO correctly construed Sections 154 and 156 in concluding that *none* of the patents at issue was entitled to have Section 156 extensions added to the URAA's newly created 20-year term. The court of appeals erred in not deferring to PTO's Final Determination that the term for patents in force on the URAA's effective date is the greater of the 17-year term that was originally issued to the patent, plus any applicable Hatch-Waxman extension, or the URAA's newly created term of 20 years from application.

U.S.C. 156(a)(2), that bars the grant of a Section 156 extension if the patent has previously been extended under Section 156(e)(1) of the Act, precludes the addition of a Section 156 extension onto the URAA's 20-year term for patents in force on June 8, 1995 solely because they were extended under Section 156 beyond their original 17-year term.

Section 156 provides that a Hatch-Waxman Act extension "shall be extended in accordance with this section from the original expiration date of the patent if * * * the term of the patent has never been extended under subsection (e)(1) of this section." 35 U.S.C. 156(a)(2). Petitioners seek to avoid Section 156(a)(2)'s bar against two extensions by arguing that shifting the extension from the end of the original 17-year term to the end of the URAA's new 20-year term does not constitute a second Hatch-Waxman extension. 96-562 Pet. 10-12. That argument, however, ignores the fact that petitioners' patents had received a Hatch-Waxman extension under Section 156(e)(1) and that those patents would have expired before June 8, 1995 had they not received that extension. Pet. App. 20a-21a; 96-575 Pet. 4; 96-562 Pet. 3-5.

Moreover, the result urged by petitioners belies the claim that shifting the extension from the end of the 17-year term to the end of the URAA's newly created 20-year term does not constitute a prohibited second extension. For example, the 17-year term for U.S. Patent No. 4,001,323 in No. 96-575 expired on January 4, 1994. On December 19, 1986, the patent received a two-year restoration under Section 156, which extended the patent's expiration date to January 4, 1996. Thus, the patent term used approximately 17 months of the extension prior to the effective date of the URAA. Pet. App. 21a. Under petitioners' theory,

however, the patent is entitled to an additional two-year extension at the end of the URAA's 20-year term in addition to the 17 months' extension already spent. Thus, the court of appeals correctly concluded that under petitioners' theory, the patent's "restoration extension totals 41 months, which exceeds the statutory limit of 24 months." *Ibid.*; see 35 U.S.C. 156(g)(6)(C).[10]

Similarly, the 17-year term for the patent in No. 96-562 expired on December 12, 1992. On December 11, 1992, that patent received a Section 156 extension of 1,069 days, extending the life of the patent to November 19, 1995. C.A. App. 401. Thus, the patent used approximately 890 days of the Section 156 extension prior to the URAA's effective date. Petitioner Organon nonetheless argues that its patent is entitled to have 1,069 days added to the URAA's 20-year term. That reasoning would extend petitioner's patent 1,959 days—890 days used prior to the effective date of the URAA plus 1,069 days at the end of the URAA's 20-year term. There is no support in the

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[10] The above illustration also counters the argument that "[a]pplying the restoration extension to the new 20-year term would not constitute a second extension to 'the term of the patent' as defined in Section 154(c) since the 20-year term had not previously been extended." 96-575 Pet. 14. A similar argument is made that "[t]he URAA * * * recalculated pre-June 8, 1995 patent terms for all purposes under the statutory scheme," including Section 156. 96-575 Pet. 12. Neither of those contentions, however, disputes the fact that the patents at issue, which would have expired before the effective date of the URAA but for their Section 156 extensions, are seeking the benefit of another Section 156 extension.

language of Section 156 or its underlying purpose for that result.[11]

Petitioners also argue that the court of appeals' opinion is "internally inconsistent" because the court interpreted the phrase "original expiration date" in Section 154 with reference to the new 20-year term, but held that, for petitioners' patents, "the former 17-year term of patent remained in effect for purposes of Section 156." 96-575 Pet. 13-14. That the court interpreted different terms in different statutory provisions, however, does not make the court's decision inconsistent. Moreover, as set forth in our conditional cross-petition, we believe that the court of appeals did not correctly interpret the phrase "original expiration date" in Section 154 because that phrase applies only to the original 17-year term granted to a patent when it was issued. However, even if, as we believe, the court of appeals' explanation is not entirely satisfactory, the remedy is not to add Hatch-Waxman extensions to the end of the URAA's 20-year term for all transitional patents. That result would be even more at odds with Section 156(a)'s requirement that extensions run "from the original

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[11] Petitioners also argue (96-562 Pet. 12; 96-575 Pet. 13-14) that the court of appeals' decision improperly differentiates between their patents and patents that on the effective date of the URAA had received, but not used, their extensions under Section 156. Although our position is that the bar against second extensions precludes the addition of an extension to the URAA's 20-year term for both classes of patents, the court of appeals rationally distinguished between petitioners' patents and those patents that had not used any of their Section 156 extension, because Section 156(a)(2)'s bar against second extensions more clearly applies to petitioners' patents.

expiration date of the patent" than the statutory construction adopted by the court of appeals.

3. a. Petitioner Organon argues (96-562 Pet. 12-20) that FDA's July 21, 1995 notice was not promulgated in compliance with the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553.[12] In that notice, FDA stated that it would not publish patent expiration dates submitted by applicants for new drug applications and new animal drug applications if the submitter stated that the expiration dates were not calculated in accordance with PTO's Final Determination. Pet. App. 74a-79a. Because the court of appeals has decided the merits of the patent law issue, the legality of FDA's notice has no continuing importance. Once the patent law issue is authoritatively resolved—whether by the court of appeals or by this Court—the FDA's decision regarding whether or not to publish expiration dates calculated in accordance with PTO's Final Determination has necessarily been superseded. Upon judicial resolution of the patent law issue, applicants for patent extensions will calculate expiration dates consistent with that resolution, and FDA will publish those dates.

b. In any event, petitioner's argument that FDA's notice is invalid because it was not promulgated in accord with the APA is misplaced. Contrary to petitioner's contention (96-562 Pet. 15-17), the notice does not constitute a new rule regarding FDA's role in publishing patent term extension dates. Absent a judicial determination to the contrary, FDA reasonably

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[12] That argument is advanced only by petitioner in No. 96-562, whose patent has expired under any construction of Sections 154 and 156. See page 9 and note 7, *supra*.

looked to PTO's Final Determination as a statement of the controlling law on the question at issue and announced that it would "not publish any patent expiration date that the submitter states is not consistent with the PTO's determination." Pet. App. 77a. That position is fully consistent with FDA's role under its regulations (21 C.F.R. 314.53(e)) and does not constitute a new rule.[13]

For similar reasons, petitioner is mistaken in arguing that the Notice constitutes a new rule regarding the procedure for challenging patent term expiration dates. 96-562 Pet. 17-18. Under 21 C.F.R. 314.53(f), the FDA does not change patent information unless the holder withdraws or amends its patent information in response to FDA's request for confirmation of the information. However, that rule does not extend to the unique circumstances present here in which the dates submitted by the transitional patent holders were expressly calculated contrary to PTO's Final Determination concerning the issue.

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[13] Petitioner also argues (96-562 Pet. 19-20) that FDA's notice promulgated a new rule interpreting the effect of the URAA on the Hatch-Waxman Act. As explained above, however, the notice simply relies on PTO's determination regarding the pertinent patent law issues, and is consistent with FDA's position that it does not make independent patent determinations.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 96-575

IN THE

Supreme Court of the United States

October Term, 1996

BRACCO DIAGNOSTICS INC. and
BRACCO INTERNATIONAL B.V.,
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v.

DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, and
BRUCE A. LEHMAN,
ASSISTANT SECRETARY OF COMMERCE and
COMMISSIONER OF PATENTS AND TRADEMARKS,
Respondents,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION IN OPPOSITION

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12 pp

COUNTERSTATEMENT OF THE QUESTION

Did the Court of Appeals correctly reject Petitioner's demand under the Uruguay Round Agreements Act ("URAA") for a second extension of the term of a drug patent previously extended under 35 U.S.C. § 156, which bars such second extensions, where Petitioner's patent would not have been in force on the effective date of URAA but for its first § 156 extension?

RULE 29.6 STATEMENT

Respondent Generic Pharmaceutical Industry Association is a New York not-for-profit corporation. It has no parent companies, subsidiaries or affiliates.

The following firms are members, associate members and affiliate members of the association: A.L. Pharma Inc., Apothecon, Barr Laboratories, Clonmel Healthcare Ltd., Copley Pharmaceutical, Inc., Creighton Products Corporation, Endo Laboratories L.L.C., ESI Lederle Generics, Geneva Pharmaceuticals, Inc., Global Pharmaceutical Corporation, Zenith Goldline, Hoechst Celanese Corporation, Lemmon Company, Perrigo Company, Rosemont Pharmaceutical Corporation, Hoechst Marion Roussel, Inc., Schein Pharmaceutical, Inc., Warner Chilcott Laboratories, Warrick Pharmaceuticals, ACIC Limited, Agvar Chemicals, Inc., Aesgen, Inc., Darby Group Companies, Inc., GYMA Laboratories of America, HMS Sales & Marketing, Inc., Interchem Corporation, KRKA, Lek USA, Inc., PharmaKinetics Laboratories, Phoenix International Life Sciences, PLIVA USA INC., Ranbaxy Pharmaceuticals, Inc., Ren-Pharm International, Ltd., Century Financial Services, Inc., Newport Data Associates, Inc., ScinoPharm International, Ltd., CCL Label, Intercall, Inc., and MIM Promark Holdings.

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Merck & Co. v. Kessler, 80 F.3d 1543 (Fed.Cir. 1996) . . . . . *passim*

Statutes and Treaties

35 U.S.C. § 154 . . . . . *passim*

35 U.S.C. § 156 . . . . . *passim*

Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984) . . . . . *passim*

Uruguay Round Agreements Act of 1994 ("URAA"), Pub. L. 103-465, 108 Stat. 4809 (1994) . . . . . *passim*

Agreement on Trade-Related Aspect of Intellectual Property Rights ("TRIPs"), H.R. Doc. No. 316, 103rd Cong., 2d Sess. 1621 (1994) 1, 5-6

BRIEF OF RESPONDENT GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION IN OPPOSITION

Respondent Generic Pharmaceutical Industry Association ("GPIA") respectfully opposes the joint petition of Bracco Diagnostics Inc. and Bracco International B.V. (collectively, "Petitioner" or "Bracco") for a writ of certiorari to the United States Court of Appeals for the Federal Circuit.

COUNTERSTATEMENT OF THE CASE

GPIA is dissatisfied with Petitioner's statement of the case in the following respects:

1. This case does not involve "international obligations" of the United States under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs"), contrary to the suggestion at pages 2-3 of the Petition. The only TRIPs provisions even remotely bearing upon this case are the articles requiring that all patents in force on the effective date of the TRIPs Agreement be given a life of not less than 20 years from the date of first application for a patent. For Petitioner's patent, that 20-year period ended on November 24, 1995. The TRIPs standard was more than satisfied in this case, since Petitioner's patent remained in effect until January 4, 1996.

2. Petitioner erroneously states at page 4 that the Food and Drug Administration ("FDA") granted it a two-year patent extension under the Hatch-Waxman Act. In fact, all

such extensions, including the one that was received for the Bracco patent, are granted by the Commissioner of Patents and Trademarks pursuant to an application made by the patent holder to the Patent and Trademark Office ("PTO") and in accordance with the standards and procedures of 35 U.S.C. § 156. FDA is not authorized to issue patents or extensions of patent terms.

3. In accordance with 35 U.S.C. § 156(e)(1), the two-year Hatch-Waxman Act extension granted to Petitioner in December 1986 became "part of the original patent" which had been issued on January 4, 1977. This extension period began to run on January 4, 1994, when Petitioner's original 17-year patent term would have otherwise expired. Thus over 17 months of the 24 months of extension which were granted to Petitioner pursuant to the Hatch-Waxman Act were used up by June 8, 1995, when the URAA became effective. Petitioner's patent was still in force on that date only by reason of its receipt and use of that Hatch-Waxman extension.

4. The case below dealt with 4 other patents similarly situated to Petitioner's — one belonging to Organon Inc., and three belonging to Syntex (U.S.A.) Inc. Organon filed a petition for certiorari in this Court (No. 96-562), but its claim, as far as the petition indicates, has plainly become moot: even under Organon's own view of the merits, the term of its patent would have expired on November 6, 1996, and Organon has suggested no circumstances that have created a live controversy. Syntex has not asked this Court to review the Federal Circuit's ruling with respect to its three affected patents. Moreover, although there are believed to be a

significant number of other patents similarly situated[1] — and similarly restricted to their single pre-URAA Hatch-Waxman extension by the terms of the underlying PTO and FDA positions, and now by the Court of Appeals — none of those patentees saw fit to bring an action or to intervene in the proceedings below. Petitioner is the only claimant of continuing patent rights that were foreclosed by the decision below who still seeks to pursue this issue.

5. The number of drug patents affected is both fixed and finite. Only patents which were granted Hatch-Waxman extensions before the June 8, 1995 effective date of URAA, and which remained in effect through that date solely through use of those extensions, are potentially affected — and only a portion of those are actually affected by the decision below. While important in dollar terms, the issues raised by Petitioner are not of broad legal significance.

6. The Bracco patent, having exhausted its Hatch-Waxman extension period, expired on January 4, 1996 under the judgment of the Federal Circuit. Organon's request to the Federal Circuit for a stay pending the filing of its petition for certiorari was denied, and no stay was sought in this Court. Thus Petitioner is trying to revive a dead patent. In fact, after the District Court's final order pursuant to the Federal Circuit's remand, the FDA on November 6, 1996 granted approval of an Abbreviated New Drug Application, ANDA No. 74-629, for a generic version of the drug covered by Bracco's now-expired patent.

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[1]See Brief for Federal Respondents in Opposition in Nos. 96-562 and 96-575 at p.9.

REASONS FOR DENYING THE WRIT

Petitioner fails to demonstrate grounds for this Court to review the portions of the decision of the Federal Circuit to which it objects. The Petition does not even contend that the Federal Circuit has decided an important federal question in a manner that conflicts with another circuit or with any decision of this court, or which should be settled by this Court, or which has in any way departed from the accepted and usual course of judicial proceedings so as to call for an exercise of this Court's supervisory power.

On the contrary, as to Bracco, the Federal Circuit made the only possible decision reasonably reconciling the provisions of two separate statutes potentially affecting Bracco's patent. Indeed, as set forth in GPIA's simultaneously filed conditional cross-petition, Respondent believes that the Federal Circuit was, if anything, overly generous to drug patentees as a group, in allowing them to cut and paste any previously granted Hatch-Waxman extensions from 17-years-from-issuance terms to the newly established 20-years-from-application terms. Although Petitioner is understandably disappointed by the fact that the appellate court having exclusive appellate jurisdiction over patent cases rejected its position, the Petition raises no general federal legal issue which merits this Court's review.

Certainly, as to this Petitioner — the ***only*** affected patentee claiming an unexpired patent who has made any effort to pursue this case — the decision of the Federal Circuit is both correct and fair. Petitioner received the full benefit of its two year Hatch-Waxman extension to January 4, 1996, without which — notwithstanding the URAA — the patent would have forever expired on January 4, 1994. And

Petitioner also received all that any patentee is guaranteed under the URAA: an expiration date which was at least 20 years from the date of first application, which in Petitioner's case would have been November 24, 1995.

Section 156(a) requires that the grant of a Hatch-Waxman extension be accomplished "in accordance with" that section of the law; but § 156 not only provides no basis or procedure for the relief Petitioner seeks, it affirmatively precludes that relief. Clearly, granting Petitioner a second 2-year Hatch-Waxman extension at the end of its newly authorized URAA 20-year term, after it had used up 17 months of its first Hatch-Waxman extension just to remain in force on the URAA effective date, would have (1) violated the explicit prohibition of § 156(a)(2) against multiple Hatch-Waxman extensions, (2) given Petitioner a total of 41 months of Hatch-Waxman extensions, when the limit applicable to Petitioner was 24 months under § 156(g)(6)(C), and (3) given Petitioner an illogical and unfair windfall which serves none of the purposes of either Hatch-Waxman or URAA, at the expense of the American public.

Petitioner thus has no reasonable basis for complaint about the decision below, and this Court has no reason to review it.

Pursuant to Rule 15.2, in addition to the matters set forth above, Respondent also draws the Court's attention to the following perceived misstatements of fact or law in the petition:

a. Petitioner wrongly but repeatedly insinuates that there is some issue of discrimination in this case, either under the TRIPs Agreement or the URAA, which implements TRIPs.

See, e.g., Petition at pp. 6, 7, 8. However, as the Petition itself reveals (p. 7), the discrimination targeted by TRIPs was "discrimination as to the place of invention, the field of technology and whether products are imported or locally produced" (quoting from Article 27:1 of TRIPs). Petitioner makes no argument that any such discrimination arises out of the Federal Circuit's decision in this case, and there is no basis whatever for making such a claim.

b. The Petition asserts at page 11 that "under the URAA the term of all patents in force on June 8, 1995 is the *greater* of" 17 years from grant of a patent plus the Hatch-Waxman extension or 20 years from application plus the Hatch-Waxman extension. The URAA contains no such provision. In fact, read literally, the only option which the URAA gives an eligible patentee is ***either*** 17 years from date of issue ***or*** 20 years from date of application — the statute actually contains no explicit provision for any Hatch-Waxman extensions. Of course, that literal reading of URAA would make no sense because it would truncate an existing Hatch-Waxman extension, such as Petitioner's, which extended an original 17 year patent to a date more than 20 years from date of application. But both PTO and the Federal Circuit avoided that result as to Petitioners by concluding that Congress did not intend to supersede Hatch-Waxman *sub silentio*, and that the pre-existing "extended" patent term separately established under § 156 remains available even if it is longer than the 20 year option.

CONCLUSION

The petition for a writ of certiorari to the Federal Circuit should be denied.

Respectfully submitted,

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